State of Arkansas
80th General Assembly
Regular Session, 1995
By: Representative Malone

A Bill

HOUSE BILL 1569

For An Act To Be Entitled

"AN ACT TO GIVE THE BOARD OF PHARMACY AUTHORITY TO LICENSE, CERTIFY, AND REGULATE MEDICAL EQUIPMENT, LEGEND DEVICES, AND/OR MEDICAL GAS SUPPLIERS; AND FOR OTHER PURPOSES."

Subtitle

"TO GIVE THE BOARD OF PHARMACY AUTHORITY TO LICENSE, CERTIFY, AND REGULATE MEDICAL EQUIPMENT, LEGEND DEVICES, AND/OR MEDICAL GAS SUPPLIERS."

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

SECTION. 1. For purposes of this act:

(a) "Home Medical Equipment, Legend Device, and Medical Gas Supplier" means a person 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 licensed suppliers of 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.

(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; and

(L) Infusion pumps.

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

(i) medical equipment used or dispensed in the normal course *of treating patients by hospitals, hospices, nursing facilities, or home health agencies;*

(ii) 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;

(iii) upper and lower extremity prosthetics and related orthotics; or

(iv) 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.

SECTION 2. Medical gases shall be labeled in compliance with existing federal and state laws.

SECTION 3. All legend devices shall be labeled in compliance with existing federal and state laws.

SECTION 4. License 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 this act. 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 residence 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 a 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.

SECTION 5. The licensure requirements of this act *and any retail pharmacy permit requirements that may apply to the distribution or provision of legend medical gases, medical equipment, legend devices, and medical supplies except legend drugs* do not apply to the following *unless the following have a separate company, corporation, division, or other business entity that is in the business of providing medical equipment for sale or*

rent to patients at their home as covered by this act:

(a) Home health agencies;

(b) Hospitals;

(c) *Manufacturers and wholesale* distributors when not selling directly to the patient;

(d) Health care practitioners legally eligible to prescribe or order home medical equipment, medical gases, and legend devices;

(e) Medical doctors, physical therapists, *respiratory therapists,* occupational therapists, speech pathologists, optometrists, chiropractors and podiatrists who use home medical equipment and/or legend devices to treat patients;

(f) Nurses who use but do not sell home medical equipment and/or legend devices to their patients;

(g) Pharmacies*;*

(h) Hospice programs;

(i) Nursing homes;

(j) Veterinarians;

(k) Dentists; and

(l) Emergency medical services.

Pharmacies, although excluded from a separate licensure requirement for medical equipment, will be subject to the same rules and regulations for the sale or rental of medical equipment covered by this act.

SECTION 6. (a) Home medical equipment, legend device, and medical gas suppliers shall not supply medical gases or legend devices to a patient without an order.

(b) Orders may be issued for institutional, medical practitioner, and individual patient use. It is also recognized that oxygen, liquid *oxygen, and legend devices may be used in emergencies by trained individuals. Nothing in this act shall prohibit the pre-hospital emergency adminstration of oxygen by licensed health care providers, emergency medical technicians, first responders, firefighters, law enforcement officers, and other emergency personnel trained in the proper use of emergency oxygen.*

SECTION 7. Regulations.

(a) The Board shall adopt regulations for the distribution of home medical equipment, legend devices, and medical gases which promote the public health and welfare and which comply with, at least, the minimum standards, terms, and conditions of federal laws and federal regulations. The regulations shall include, without limitation:

(1) Minimum information from each home medical equipment, legend device, and medical gas supplier required for licensing and renewal of licenses.

(2) Minimum qualifications of persons who engage in the distribution of these products.

(3) Appropriate education or experience, or both, of persons employed in distribution of these products who assume responsibility for positions related to compliance with state licensing requirements.

(4) Minimum requirements for the storage and handling of these products.

(5) Minimum requirements for the establishment and maintenance of distribution records for these products.

(6) *Federal and state* labeling requirements.

(b) State regulations shall not apply to the following:

(a) Home health agencies;

(b) Hospitals;

(c) Manufacurers and wholesale distributors when not selling directly to the patient;

(d) Health care practitioners legally eligible to prescribe or order home medical equipment, medical gases, and legend devices;

(e) Medical doctors, physical therapists, respiratory therapists, occupational therapists, speech pathologists, optometrists, chiropractors and podiatrists who use home medical equipment and/or legend devices to treat patients;

(f) Nurses who use but do not sell home medical equipment and/or legend devices to their patients;

(g) Hospice programs;

(h) Nursing homes; and

(i) Veterinarians.

SECTION 8. Advisory Committee to the Board.

There is created an Advisory Committee to the Board of Pharmacy to be *composed of seven (7) members. Five (5) members, one of which shall be a hospital-based medical equipment supplier, and none of which can be a registered pharmacist or a representative of a company which is primarily in the business of pharmacy, shall be appointed by the Board from a list of at least eight (8) names furnished by a nominating committee comprised of two (2) members of the Medical Equipment Suppliers Association of Arkansas and two (2) members of the HomeCare Association of Arkansas, and two (2) members of the Board of Pharmacy. The remianing two (2) members of the Advisory Committee shall be appointed by the* Board of Pharmacy. All members shall be actively involved in businesses licensed by this act. The committee shall review and make recommendations to the Board on the merit of all regulations dealing with medical equipment, legend devices and medical gases which are proposed by the Board and before they are adopted by the Board.

SECTION 9. Revocation or Suspension of Licensed.

The Board may revoke or suspend licenses, or may refuse to issue any license under this act, if the holder or applicant 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, medical gases, medical supplies except legend drugs and legend devices*;

(2) Violation of any provisions of this act or any regulation promulgated hereunder;

(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.

SECTION 10. (a) After the effective date of this act, the manufacturer within this state, shipment into this state, sale or offer for sale within this state of medical gases shall not be subject to Arkansas Code 20-56-211 (11)(C).

(b) Pursuant to this act, the dispensing of medical gases does not require a retail pharmacy permit. After the effective date of this act, the sale of medical gases directly to patients shall not be subject to Arkansas

Code §§ 20-56-211(11)(C) or 20-64-504.

SECTION 11. Wholesale distributors licensed under Arkansas Code 20-64-501 et seq. may exchange those licenses for licenses issued under this act without payment of additional fees.

SECTION 12. No regulations promulgated to implement this act shall be effective until they have been reviewed by the Joint Interim Committee on Public Health, Welfare and Labor.

SECTION *13*. All provisions of this act of a general and permanent nature are amendatory to the Arkansas Code of 1987 Annotated and the Arkansas Code Revision Commission shall incorporate the same in the Code.

SECTION *14*. If any provision of this act or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of the act which can be given effect without the invalid provision or application, and to this end the provisions of this act are declared to be severable.

SECTION *15*. All laws and parts of laws in conflict with this act are hereby repealed.

/s/Rep. Malone