

1 **State of Arkansas**
2 **80th General Assembly**
3 **Regular Session, 1995**
4 **By: Representative Malone**

A Bill

ACT 1101 OF 1995
HOUSE BILL 1569

For An Act To Be Entitled

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

Subtitle

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

18
19 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

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21 SECTION. 1. For purposes of this act:

22 (a) "Home Medical Equipment, Legend Device, and Medical Gas Supplier"
23 means a person licensed to supply home medical equipment, medical gases and/or
24 legend devices to patients on an order from medical practitioners licensed to
25 order, use, or administer these products and to other licensed suppliers of
26 home medical equipment, medical gases, and/or legend devices.

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

31 (c) "Legend Device" means a device which, because of any potential for
32 harmful effect or the method of its use, is not safe - except under the
33 supervision of a practitioner.

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

36 (A) Oxygen and oxygen delivery systems;

- 1 (B) Ventilators;
- 2 (C) Respiratory disease management devices;
- 3 (D) Electronic and computer driven wheelchairs and seating
- 4 systems;
- 5 (E) Apnea monitors;
- 6 (F) Transcutaneous electrical nerve stimulator (T.E.N.S.)
- 7 units;
- 8 (G) Low air loss cutaneous pressure management devices;
- 9 (H) Sequential compression devices;
- 10 (I) Neonatal home phototherapy devices;
- 11 (J) Feeding pumps;
- 12 (K) Electrically-powered hospital beds; and
- 13 (L) Infusion pumps.

- 14 (2) The term "medical equipment" does not include:
- 15 (i) medical equipment used or dispensed in the normal course
- 16 *of treating patients by hospitals, hospices, nursing facilities, or home*
- 17 *health agencies;*
- 18 (ii) medical equipment used or dispensed by health care
- 19 professionals, licensed in Arkansas--provided the professional is practicing
- 20 within the scope of that professional_s practice act;
- 21 (iii) upper and lower extremity prosthetics and related
- 22 orthotics; or
- 23 (iv) canes, crutches, walkers, bathtub grab bars, standard
- 24 wheelchairs, commode chairs, and bath benches.
- 25 (e) "Medical Gas" means those gases and liquid oxygen intended for
- 26 human consumption.
- 27 (f) "Order" means an order issued by a licensed medical practitioner
- 28 legally authorized to order medical gases and/or legend devices.

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30 *SECTION 2. Medical gases shall be labeled in compliance with existing*

31 *federal and state laws.*

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33 *SECTION 3. All legend devices shall be labeled in compliance with*

34 *existing federal and state laws.*

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1 SECTION 4. License Required.

2 (a) No person or entity subject to licensure shall sell or rent or
3 offer to sell or rent directly to patients in this state any home medical
4 equipment, legend devices, and/or medical gases unless the person or entity is
5 licensed as required by this act. The licensure requirements of this act will
6 apply to all companies, agencies, and other business entities that are in the
7 business of supplying medical equipment to patients in their residence and
8 which bill the patient or the patient's insurance, Medicare, Medicaid, or
9 other third-party payor for the rent or sale of that equipment. The
10 application for a license shall be on a form furnished by the Board and shall
11 be accompanied by payment of a fee of two hundred dollars (\$200). The Board
12 shall require a separate license for each facility directly or indirectly
13 owned or operated within this state by the same person or business entity
14 within this state, or for a parent entity with divisions, subdivisions,
15 subsidiaries, and/or affiliate companies when operations are conducted at more
16 than one location and there exists joint ownership and control among all the
17 entities.

18 (b)(1) The annual license renewal fee is one hundred dollars (\$100).

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

21 (3) Each application for renewal of the license must be made on or
22 before December 31 of each year. Penalties for late payment include: Twenty
23 dollars (\$20.00) penalty if not paid by February 1 of each year, forty dollar
24 (\$40.00 penalty if not paid by March 1 of each year. The license shall be
25 considered null and void if the fee is not paid by April 1 of each year.

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

28

29 SECTION 5. The licensure requirements of this act and any retail
30 pharmacy permit requirements that may apply to the distribution or provision
31 of legend medical gases, medical equipment, legend devices, and medical
32 supplies except legend drugs do not apply to the following unless the
33 following have a separate company, corporation, division, or other business
34 entity that is in the business of providing medical equipment for sale or rent
35 to patients at their home as covered by this act:

- 1 (a) Home health agencies;
- 2 (b) Hospitals;
- 3 (c) *Manufacturers and wholesale* distributors when not selling directly
- 4 to the patient;
- 5 (d) Health care practitioners legally eligible to prescribe or order
- 6 home medical equipment, medical gases, and legend devices;
- 7 (e) Medical doctors, physical therapists, *respiratory therapists,*
- 8 occupational therapists, speech pathologists, optometrists, chiropractors and
- 9 podiatrists who use home medical equipment and/or legend devices to treat
- 10 patients;
- 11 (f) Nurses who use but do not sell home medical equipment and/or legend
- 12 devices to their patients;
- 13 (g) Pharmacies;
- 14 (h) *Hospice programs;*
- 15 (i) *Nursing homes;*
- 16 (j) *Veterinarians;*
- 17 (k) *Dentists; and*
- 18 (l) *Emergency medical services.*

19 *Pharmacies, although excluded from a separate licensure requirement for*

20 *medical equipment, will be subject to the same rules and regulations for the*

21 *sale or rental of medical equipment covered by this act.*

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23 SECTION 6. (a) Home medical equipment, legend device, and medical gas

24 suppliers shall not supply medical gases or legend devices to a patient

25 without an order.

26 (b) Orders may be issued for institutional, medical practitioner, and

27 individual patient use. It is also recognized that oxygen, liquid oxygen, and

28 *legend devices may be used in emergencies by trained individuals. Nothing in*

29 *this act shall prohibit the pre-hospital emergency administration of oxygen by*

30 *licensed health care providers, emergency medical technicians, first*

31 *responders, firefighters, law enforcement officers, and other emergency*

32 *personnel trained in the proper use of emergency oxygen.*

33

34 SECTION 7. Regulations.

35 (a) The Board shall adopt regulations for the distribution of home

1 medical equipment, legend devices, and medical gases which promote the public
2 health and welfare and which comply with, at least, the minimum standards,
3 terms, and conditions of federal laws and federal regulations. The
4 regulations shall include, without limitation:

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

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

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

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

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

17 (6) *Federal and state labeling requirements.*

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

19 (a) *Home health agencies;*

20 (b) *Hospitals;*

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

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

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

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

31 (g) *Hospice programs;*

32 (h) *Nursing homes; and*

33 (i) *Veterinarians.*

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35 SECTION 8. Advisory Committee to the Board.

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

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16 SECTION 9. Revocation or Suspension of Licensed.

17 The Board may revoke or suspend licenses, or may refuse to issue any
18 license under this act, if the holder or applicant has committed or is found
19 guilty by the Board of any of the following:

20 (1) Violation of any federal, state, or local law or regulation
21 relating to *medical equipment, medical gases, medical supplies except legend*
22 *drugs and legend devices;*

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

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

27

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

32 (b) *Pursuant to this act, the dispensing of medical gases does not*
33 *require a retail pharmacy permit. After the effective date of this act, the*
34 *sale of medical gases directly to patients shall not be subject to Arkansas*
35 *Code §§ 20-56-211(11) (C) or 20-64-504.*

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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

APPROVED: 4-10-95

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