GENERAL ASSEMBLY OF NORTH CAROLINA

SESSION 1993

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HOUSE BILL 1082*
Second Edition Engrossed 5/18/93

Short Title: Regulate Medical Equipment. (Public)

Sponsors: Representatives McAllister; Arnold, Barnhill, Beall, Bowie, Bowman, D. Brown, Brubaker, Burton, Colton, Cummings, Cunningham, DeVane, Easterling, Esposito, Fitch, Flaherty, Gamble, Gardner, Gist, Gottovi, Green, Hill, Holt, Howard, Judy Hunt, H. Hunter, Jeffus, Kennedy, Kinney, Mavretic, McLawhorn, Michaux, Nesbitt, Nichols, Oldham, Richardson, Spears, Stewart, Wainwright, and Warner.

Referred to: Health and Human Services.

April 19, 1993

A BILL TO BE ENTITLED

AN ACT TO GIVE THE BOARD OF PHARMACY AUTHORITY TO REGULATE MEDICAL EQUIPMENT INTENDED FOR USE IN AN INDIVIDUAL'S HOME.

The General Assembly of North Carolina enacts:

Section 1. G.S. 90-85.22 reads as rewritten:

"**§ 90-85.22. ~~Devices; registration.~~ Device and medical equipment permits.**

(a) Devices. – Each place where devices are dispensed shall register annually with the Board on a form provided by the ~~Board; provided this section shall not apply to places with current pharmacy permits.~~ Board and obtain a device permit. A business that has a current pharmacy permit does not have to register and obtain a device permit. Records of devices dispensed in pharmacies or other places shall be kept in accordance with ~~regulations promulgated by the Board of Pharmacy.~~ rules adopted by the Board.

(b) Medical Equipment. – Each place that delivers medical equipment to the user of the equipment shall register annually with the Board on a form provided by the Board and obtain a medical equipment permit. A business that has a current pharmacy permit or a current device permit does not have to register and obtain a medical equipment permit. Medical equipment shall be delivered only in accordance with requirements established by rules adopted by the Board."

Sec. 2. G.S. 90-85.3 reads as rewritten:

"**§ 90-85.3. Definitions.**

(a) 'Administer' means the direct application of a drug to the body of a patient by injection, inhalation, ingestion or other means.

(b) 'Board' means the North Carolina Board of Pharmacy.

(c) 'Compounding' means taking two or more ingredients and combining them into a dosage form of a drug, exclusive of compounding by a drug manufacturer, distributor, or packer.

(d) 'Deliver' means the actual, constructive or attempted transfer of a ~~drug or device~~ drug, a device, or medical equipment from one person to another.

(e) 'Device' means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article including any component part or accessory, whose label or labeling bears the statement 'Caution: federal law requires dispensing by or on the order of a physician.' The term does not include:

(1) Devices used in the normal course of treating patients by health care facilities and agencies licensed under Chapter 131E or Article 2 of Chapter 122C of the General Statutes;

(2) Devices used or provided in the treatment of patients by medical doctors, dentists, physical therapists, occupational therapists, speech pathologists, optometrists, chiropractors, podiatrists, and nurses licensed under Chapter 90 of the General Statutes, provided they do not dispense devices used to administer or dispense drugs.

(f) 'Dispense' means preparing and packaging a prescription drug or device in a container and labeling the container with information required by State and federal law. Filling or refilling drug containers with prescription drugs for subsequent use by a patient is 'dispensing'. Providing quantities of unit dose prescription drugs for subsequent administration is 'dispensing'.

(g) 'Drug' means:

(1) Any article recognized as a drug in the United States Pharmacopeia, or in any other drug compendium or any supplement thereto, or an article recognized as a drug by the United States Food and Drug Administration;

(2) Any article, other than food or devices, intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals;

(3) Any article, other than food or devices, intended to affect the structure or any function of the body of man or other animals; and

(4) Any article intended for use as a component of any articles specified in clause (1), (2) or (3) of this subsection.

(h) 'Emancipated minor' means any person under the age of 18 who is or has been married or who is or has been a parent; or whose parents or guardians have surrendered their rights to the minor's services and earnings as well as their right to custody and control of the minor's person; or who has been emancipated by an appropriate court order.

(i) 'Health care provider' means any licensed health care professional; any agent or employee of any health care institution, health care insurer, health care professional school; or a member of any allied health profession.

(j) 'Label' means a display of written, printed or graphic matter upon the immediate or outside container of any drug.

(k) 'Labeling' means preparing and affixing a label to any drug container, exclusive of labeling by a manufacturer, packer or distributor of a nonprescription drug or a commercially packaged prescription drug or device.

(l) 'License' means a license to practice pharmacy including a renewal license issued by the Board.

(l1) 'Medical equipment' means any of the following items that are intended for use by the consumer in the consumer's place of residence:

(1) A device.
(2) Ambulation assistance equipment.
(3) Mobility equipment.
(4) Rehabilitation seating.
(5) Oxygen and respiratory care equipment.
(6) Rehabilitation environmental control equipment.
(7) Diagnostic equipment.
(8) A bed prescribed by a physician to treat or alleviate a medical condition.

The term 'medical equipment' does not include (i) medical equipment used or dispensed in the normal course of treating patients by hospitals and nursing facilities licensed under Chapter 131E of the General Statutes or hospitals or agencies licensed under Article 2 of Chapter 122C of the General Statutes, other than medical equipment delivered or dispensed by a separate unit or subsidiary corporation of a hospital or nursing facility or agency that is in the business of delivering medical equipment to an individual's residence; (ii) medical equipment used or dispensed by professionals licensed under Chapter 90 of the General Statutes, 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, and bathtub grab bars.

(m) 'Permit' means a permit to operate a ~~pharmacy~~ pharmacy, deliver medical equipment, or dispense devices, including a renewal license issued by the Board.

(n) 'Person' means an individual, corporation, partnership, association, unit of government, or other legal entity.

(o) 'Person **in loco parentis**' means the person who has assumed parental responsibilities for a child.

(p) 'Pharmacist' means a person licensed under this Article to practice pharmacy.

(q) 'Pharmacy' means any place where prescription drugs are dispensed or compounded.

(r) 'Practice of pharmacy' means the responsibility for: interpreting and evaluating drug orders, including prescription orders; compounding, dispensing and labeling prescription drugs and devices; properly and safely storing drugs and devices;

maintaining proper records; and controlling pharmacy goods and services. A pharmacist may advise and educate patients and health care providers concerning therapeutic values, content, uses and significant problems of drugs and devices; assess, record and report adverse drug and device reactions; take and record patient histories relating to drug and device therapy; monitor, record and report drug therapy and device usage; perform drug utilization reviews; and participate in drug and drug source selection and device and device source selection as provided in G.S. 90-85.27 through G.S. 90-85.31. A pharmacist who has received special training may be authorized and permitted to administer drugs pursuant to a specific prescription order in accordance with rules and regulations adopted by each of the Boards of Pharmacy, the Board of Nursing, and the Board of Medical Examiners of the State of North Carolina. Such rules and regulations shall be designed to ensure the safety and health of the patients for whom such drugs are administered.

(s) 'Prescription drug' means a drug that under federal law is required, prior to being dispensed or delivered, to be labeled with the following statement:

'Caution: Federal law prohibits dispensing without prescription.'

(t) 'Prescription order' means a written or verbal order for a prescription drug, prescription device, or pharmaceutical service from a person authorized by law to prescribe such drug, device, or service. A prescription order includes an order entered in a chart or other medical record of a patient.

(u) 'Unit dose medication system' means a system in which each dose of medication is individually packaged in a properly sealed and properly labeled container."

Sec. 3. G.S. 90-85.24 reads as rewritten:

"**§ 90-85.24. Fees collectible by Board.**

The Board of Pharmacy shall be entitled to charge and collect not more than the following fees: for the examination of an applicant for license as a pharmacist, one hundred fifty dollars ($150.00) plus the cost of the test material; for renewing the license as a pharmacist, sixty-five dollars ($65.00); for renewing the license of an assistant pharmacist, ten dollars ($10.00); for licenses without examination as provided in G.S. 90-85.20, original, three hundred dollars ($300.00); for original registration of a drugstore, two hundred fifty dollars ($250.00), and renewal thereof, one hundred twenty-five dollars ~~($125.00).~~ ($125.00); for registration to dispense devices, deliver medical equipment, or both, three hundred dollars ($300.00) per year. All fees shall be paid before any applicant may be admitted to examination or ~~his name~~ the applicant's name may be placed upon the register of pharmacists or before any license or permit, or any renewal thereof, may be issued by the Board."

Sec. 4. G.S. 90-85.40 is amended by adding a new subsection to read:

"(d1) It is unlawful for a person to own or manage a place of business from which medical equipment is delivered without a permit as required by this Article."

Sec. 5. This act becomes effective January 1, 1994.