GENERAL ASSEMBLY OF NORTH CAROLINA

SESSION 1991

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HOUSE BILL 1465

Short Title: Pharmacy/Medicaid Reqmnts. (Public)

Sponsors: Representatives Woodard; and Bowman.

Referred to: Human Resources.

June 2, 1992

A BILL TO BE ENTITLED

AN ACT TO AMEND THE PHARMACY PRACTICE ACT TO CONFORM WITH FEDERAL REQUIREMENTS TO AVOID LOSS OF MEDICAID FUNDS.

Whereas, the Omnibus Budget Reconciliation Act of 1990 mandates that states enact statutory requirements providing for the availability of counseling by pharmacists and other authorized persons when dispensing prescription medications to patients; and

Whereas, the Omnibus Reconciliation Act of 1990 requires that pharmacy counseling services be made available by State law effective January 1, 1993; and

Whereas, states that do not enact pharmacy counseling requirements by January 1, 1993, are subject to loss of federal Medicaid funds; Now, therefore,

The General Assembly of North Carolina enacts:

Section 1. 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 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.

(l.1) 'Patient counseling' means the oral transfer of relevant information to a patient or the patient's agent at the time a prescription is provided, by a person authorized to dispense prescription drugs or devices under North Carolina law.

(m) 'Permit' means a permit to operate a pharmacy 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. 2. G.S. 90-85.32 reads as rewritten:

"**§ 90-85.32. ~~Filling and refilling regulations.~~ Rules governing filling, refilling, and transfer of prescription orders, and patient counseling.**

The Board may ~~promulgate~~ adopt rules governing the filling, ~~refilling~~ refilling, and transfer of prescription ~~orders~~ orders, and governing patient counseling regarding prescription drugs and devices dispensed, not inconsistent with other provisions of law

regarding the distribution of drugs and devices. Such regulations shall assure the safe and secure distribution of drugs and devices. Prescriptions marked PRN shall not be refilled more than one year after the date issued by the prescriber unless otherwise specified."

Sec. 3. Article 4A of Chapter 90 of the General Statutes is amended by adding the following new section to read:

"**§ 90-85.32A. Patient Counseling Services.**

(a) Persons authorized to dispense prescription drugs and devices under this Article shall, before dispensing the prescription order, offer to counsel the patient or the patient's agent regarding the prescription. The offer to counsel shall be made directly to the patient or the patient's agent in person whenever practicable, or by telephone. Counseling provided under this section may include, but is not limited to:

(1) The name, strength, route of administration and dosage form of the medicine,
(2) The storage of the medicine,
(3) The directions for use and duration of therapy,
(4) Refill instructions,
(5) What to do if a dose is missed,
(6) Common side effects to look for and what to do if they occur,
(7) Possible interactions with food and other medicine (including non-prescription medicine),
(8) Special directions for preparation, administration or use by the patient, and
(9) Instructions for self-monitoring of therapy.

Persons providing counseling under this section may use written materials, audio visual aids, signs, patient leaflets, and other educational materials to supplement counseling, but shall not use such materials as a replacement for counseling.

(b) Counseling provided under this section shall be done in the manner most appropriate to the specific patient as determined in the professional judgment of the person authorized to dispense the prescription drug or device. In providing counseling under this section, the person dispensing the prescription drug or device shall make reasonable efforts to obtain from the patient or patient's agent, to record, and to maintain at least the following patient information:

(1) Name, address, telephone number, gender, and age or date of birth,
(2) Current list of medicines and devices relevant to drug therapy being used,
(3) Relevant disease states,
(4) Allergies and drug reactions,
(5) Comments relevant to the patient's medication therapy, and
(6) Any other information necessary to provide counseling.

Patient counseling provided pursuant to this section shall impose no additional liability upon the person authorized to dispense the prescription drugs or devices arising from the rendering of the counseling service.

(c) Nothing in this section shall be construed to require a person authorized to dispense prescription drugs or devices to provide counseling when the patient or the patient's agent refuses the person's offer of counseling."

Sec. 4. This act becomes effective January 1, 1993.