rrc staff OPINION

*Please Note: This communication is either 1) only the recommendation of an RRC staff attorney as to action that the attorney believes the Commission should take on the cited rule at its next meeting, or 2) an opinion of that attorney as to some matter concerning that rule. The agency and members of the public are invited to submit their own comments and recommendations (according to RRC rules) to the Commission.*

AGENCY: NC MEDICAL BOARD and NC BOARD OF PHARMACY

RULE CITATION: 21 NCAC 32U .0101 and 21 NCAC 46 .2507

RECOMMENDED ACTION:

 x Approve, but note staff’s comment

 Object, based on:

 Lack of statutory authority

 Unclear or ambiguous

 Unnecessary

 Failure to comply with the APA

 Extend the period of review

COMMENT:

These are identical rules adopted by the Medical Board and Board of Pharmacy pursuant to G.S. 90-85.3(r) that requires the rules to be adopted by each of the Boards of Pharmacy, the Board of Nursing, and the NC Medical Board. The Board of Nursing has taken the position that a rule about pharmacists administering vaccines is outside its realm of expertise. It has in place a current rule (21 NCAC 36 .0221(e)) that authorizes pharmacists to administer vaccines in accordance with this rule from the Board of Pharmacy. That provision has historically been seen as satisfactory adoption of whatever rule the Board of Pharmacy adopted.

Robert A. Bryan, Jr.

Commission Counsel

**§ 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.

(b1)      "Clinical pharmacist practitioner" means a licensed pharmacist who meets the guidelines and criteria for such title established by the joint subcommittee of the North Carolina Medical Board and the North Carolina Board of Pharmacy and is authorized to enter into drug therapy management agreements with physicians in accordance with the provisions of G.S. 90-18.4.

(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, 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.

(l 1)      "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 or on behalf of home care agencies, 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; (ii) medical equipment used or dispensed by professionals licensed under Chapters 90 or 93D 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.

(l 2)      "Mobile pharmacy" means a pharmacy that meets all of the following conditions:

(1)        Is either self-propelled or moveable by another vehicle that is self-propelled.

(2)        Is operated by a nonprofit corporation.

(3)        Dispenses prescription drugs at no charge or at a reduced charge to persons whose family income is less than two hundred percent (200%) of the federal poverty level and who do not receive reimbursement for the cost of the dispensed prescription drugs from Medicare, Medicaid, a private insurance company, or a governmental unit.

(m)       "Permit" means a permit to operate a 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.

(q1)      "Pharmacy personnel" means pharmacists and pharmacy technicians.

(q2)      "Pharmacy technician" means a person who may, under the supervision of a pharmacist, perform technical functions to assist the pharmacist in preparing and dispensing prescription medications.

(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 adopted by each of the Boards of Pharmacy, the Board of Nursing, and the North Carolina Medical Board. The rules shall be designed to ensure the safety and health of the patients for whom such drugs are administered. An approved clinical pharmacist practitioner may collaborate with physicians in determining the appropriate health care for a patient, subject to the provisions of G.S. 90-18.4.

(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. (1981 (Reg. Sess., 1982), c. 1188, s. 1; 1983, c. 196, ss. 1-3; 1991, c. 578, s. 1; 1993 (Reg. Sess., 1994), c. 692, s. 2; 1995, c. 94, s. 24; 1999-246, s. 1; 1999-290, ss. 4, 5; 2001-375, s. 1; 2002-159, s. 37.)

**21 NCAC 36 .0221 LICENSE REQUIRED**

(a) No cap, pin, uniform, insignia or title shall be used to represent to the public, that an unlicensed person is a registered nurse or a licensed practical nurse as defined in G.S. 90-171.43.

(b) The repetitive performance of a common task or procedure which does not require the professional judgment of a registered nurse or licensed practical nurse shall not be considered the practice of nursing for which a license is required. Tasks that may be delegated to the Nurse Aide I and Nurse Aide II shall be established by the Board of Nursing pursuant to 21 NCAC 36 .0403. Tasks may be delegated to an unlicensed person which:

(1) frequently recur in the daily care of a client or group of clients;

(2) are performed according to an established sequence of steps;

(3) involve little or no modification from one client-care situation to another;

(4) may be performed with a predictable outcome; and

(5) do not inherently involve ongoing assessment, interpretation, or decision-making which cannot be logically separated from the procedure(s) itself.

Client-care services which do not meet all of these criteria shall be performed by a licensed nurse

(c) The registered nurse or licensed practical nurse shall not delegate the professional judgment required to implement any treatment or pharmaceutical regimen which is likely to produce side effects, toxic effects, allergic reactions, or other unusual effects; or which may rapidly endanger a client's life or well-being and which is prescribed by a person authorized by state law to prescribe such a regimen. The nurse who assumes responsibility for implementing a treatment or pharmaceutical regimen shall be accountable for:

(1) recognizing side effects;

(2) recognizing toxic effects;

(3) recognizing allergic reactions;

(4) recognizing immediate desired effects;

(5) recognizing unusual and unexpected effects;

(6) recognizing changes in client's condition that contraindicates continued administration of the pharmaceutical or treatment regimen;

(7) anticipating those effects which may rapidly endanger a client's life or well-being; and

(8) making judgments and decisions concerning actions to take in the event such effects occur.

(d) When health care needs of an individual are incidental to the personal care needs of the individual, nurses shall not be accountable for care performed by clients themselves, their families or significant others, or by caretakers who provide personal care to the individual.

(e) Pharmacists may administer drugs in accordance with 21 NCAC 46 .2507.

*History Note: Authority G.S. 90-85.3; 90-171.23(b); 90-171.43; 90-171.83;*

*Eff. May 1, 1982;*

*Amended Eff. July 1, 2004; April 1, 2002; December 1, 2000; July 1, 2000; January 1, 1996; February 1, 1994; April 1, 1989; January 1, 1984;*

*Emergency Amendment Eff. September 10, 2004;*

*Amended Eff. April 1, 2008; December 1, 2004.*