

MINUTES

North Carolina Medical Board

August 30, 2004

**1203 Front Street
Raleigh, North Carolina**

Minutes of the Open Sessions of the North Carolina Medical Board Meeting August 30, 2004.

An Emergency meeting of the North Carolina Medical Board was held via telephone conference call. The meeting was called to order at 5:00 p.m., Monday, August 30, 2004, by Stephen M. Herring, MD, President. Board members in attendance were: E. K. Fretwell, PhD; Robin N. Hunter Buskey, PA-C; Michael E. Norins, MD; Janelle A. Rhyne, MD; Ms. Shikha Sinha; Edwin R. Swann, MD; and Mr. Aloysius P. Walsh. Absent were: Charles L. Garrett, MD, President Elect; Robert C. Moffatt, MD, Secretary; H. Arthur McCulloch, MD, Treasurer and George L. Saunders, III, MD. Several attempts were made to notify all Board Members.

Staff members present were: R. David Henderson, JD, Executive Director; Thomas W. Mansfield, JD, Legal Department Director; Marcus Jimison, JD, Board Attorney; Mr. Donald Smelcer, Technology Department Director; and Mr. Jeffery Denton, Executive Assistant/Verification Coordinator.

Also, in attendance was M. Denise Stanford of Bailey & Dixon, LLP, representing the North Carolina Board of Pharmacy.

Administration of Influenza Vaccines By Pharmacists – Emergency Rule

The Board of Pharmacy emergency rule for Administration of Influenza Vaccines and the Statement of Findings of Need for Emergency Rule were reviewed and discussed.

Motion: (MN, RHB) A motion passed to approve the following Emergency Rule as presented.

STATEMENT OF FINDINGS OF NEED FOR EMERGENCY RULE

BY THE NORTH CAROLINA MEDICAL BOARD (MEDICAL BOARD): Pursuant to G.S. §150B-21.1A, the Medical Board hereby issues this Statement Of Findings Of Need For Emergency Rule 21 NCAC 32U.0101 regarding administration of drugs by pharmacists.

FINDINGS

1. G.S. §90-85.3 (r) provides that 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 the Board of Pharmacy (Pharmacy Board), the Nursing Board, and the Medical Board. Such rules must be designed to ensure the safety and health of the patients for whom such drugs are administered.

2. Pursuant to its authority under G.S. §90-85.3, the Pharmacy Board adopted 21 NCAC 46.2507 (Rule .2507), Administration of Immunizations by Pharmacists, as follows:

A pharmacist who has successfully completed a course of training approved by the Board, and the North Carolina Medical Board, or the North Carolina Board of Nursing, may administer immunizations.

3. Rule .2507 became effective on April 1, 2003. Currently, no course of training has been approved by all three Boards to allow the administration of immunizations by pharmacists.

4. On October 1, 2003, the Pharmacy Board published a proposed amendment to Rule .2507 in Volume 18, Issue 7 of the North Carolina Register as follows:

A pharmacist who has successfully completed a course of training approved by the Board, and the North Carolina Medical Board, or the North Carolina Board of Nursing, in immunizations approved by the Board and the Center for Disease Control and Prevention may administer immunizations.

5. Following discussions with and input from the Medical and Nursing Boards, Rule .2507 was further revised with the approval of all three Boards to reflect the rule which attached hereto. On May 11, 2004, the Pharmacy Board adopted Rule .2507 as an emergency rule. Rule .2507 is currently in effect.

6. On August 2, 2004, the Nursing Board published notice in Volume 19, Issue 3 of the North Carolina Register of its intent to revise 21 NCAC 36.0221 (.0221) to allow pharmacists to administer drugs in accordance with 21 NCAC 46.2507.

7. During the 2003-04 influenza season, the onset of influenza began earlier than usual. There was an unprecedented demand for the influenza vaccine. Additional vaccine was purchased by the Centers for Disease Control, but was not administered to patients during the influenza season.

8. Epidemics of influenza typically occur during the winter months in temperate regions and have been responsible for an average of approximately 36,000 deaths per year in the United States during 1990-1999. Influenza viruses cause disease among all age groups. Rates of serious illness and death are highest among persons over 65 years of age and persons of any age who have medical conditions that place them at risk for complications from influenza.

9. The projected supply for the United States market in 2004-05 is 83 to 100 million doses of trivalent vaccine. The total vaccine available in the United States has doubled in the last ten years to meet market demand.

10. On December 5, 2003, the Center for Disease Control (CDC) issued the following health advisory: In a typical year, 70-75 million Americans receive a flu shot. This year manufacturers produced approximately 83 million doses of flu vaccine. The United States has never used more than 80 million doses of flu vaccine in a season. CDC officials note that it is not unusual at this time of year for influenza vaccine supplies to be limited as many health care providers begin to wind down their vaccination programs. Therefore, people wishing to be vaccinated may need to be persistent to find vaccine. CDC has observed an earlier onset of the flu this year; therefore the agency continues to encourage individuals at high risk for complications from influenza and health care workers to receive a flu vaccination, while supplies remain available.

11. The administration and availability of influenza vaccines is a matter of public health, safety, and welfare.

12. Last year's increase in demand for influenza vaccines was a serious and unforeseen threat to the public health and safety. Failure to meet the increased demand for influenza vaccines this year could cause a serious and unforeseen threat to the public health and safety.

13. A recent article published in *Vaccine* (*Vaccine* 22 (2004) 1001-1006) found that individuals aged 65 years and older who lived in states where pharmacists could provide vaccines had significantly higher influenza vaccine rates than individuals of this age who resided in states where pharmacists could not provide vaccines. The authors concluded that allowing pharmacists to provide vaccinations is associated with higher influenza vaccination rates for individuals aged 65 years and older.

14. The administration of influenza vaccines by pharmacists will allow for greater access to influenza vaccines for the public. Pharmacists have unparalleled access and influence, proximity, and extended evening and weekend hours. The names of people who are

at risk are in the pharmacy's database. People were 74% more likely to be vaccinated if prompted by their pharmacist, than if not prompted.

15. Adult vaccines are a cost-effective means of preventing disease. To realize these benefits, vaccines must be made readily available to the public.

16. If the Medical Board adhered to the notice and hearing requirements, this rule change would not be effective until at least February 1, 2005, at the end of the flu season.

17. It would be contrary to the public interest to delay implementation of this rule change. It is in the public interest to enable pharmacists to administer influenza vaccines.

CONCLUSIONS

1. If the Medical Board follows the current notice and hearing requirements of the Administrative Procedure Act, the adoption of this rule change would not be effective until February 1, 2005 or later.

2. Adherence to the notice and hearing requirements of the Administrative Procedure Act would be contrary to the public interest.

3. The immediate adoption of this rule change is required to enable the pharmacists to administer influenza vaccines during the entire flu season.

21 NCAC 32U.0101 ADMINISTRATION OF VACCINES BY PHARMACISTS

(a) Purpose. The purpose of this section is to provide standards for pharmacists engaged in the administration of influenza vaccines as authorized in § 90-85.3(r) of the North Carolina Pharmacy Practice Act.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

- (1) "ACPE" means Accreditation Council for Pharmacy Education.
- (2) "Administer" means the direct application of a drug to the body of a patient by injection, inhalation, ingestion, or other means by:
 - (A) a pharmacist, an authorized agent under his/her supervision, or other person authorized by law; or
 - (B) the patient at the direction of a practitioner.
- (3) "Antibody" means a protein in the blood that is produced in response to stimulation by a specific antigen. Antibodies help destroy the antigen that produced them. Antibodies against an antigen usually equate to immunity to that antigen.
- (4) "Antigen" means a substance recognized by the body as being foreign; it results in the production of specific antibodies directed against it.
- (5) "Board" means the North Carolina Board of Pharmacy.
- (6) "Confidential record" means any health-related record that contains information that identifies an individual and that is maintained by a pharmacy or pharmacist such as a patient medication record, prescription drug order, or medication order.
- (7) "Immunization" means the act of inducing antibody formation, thus leading to immunity.
- (8) "Medical Practice Act" means the North Carolina Medical Practice Act.

- (9) "Physician" means a currently licensed M.D. or D.O. in good standing with the North Carolina Medical Board who is responsible for the on-going, continuous supervision of the pharmacist pursuant to written protocols between the pharmacist and the physician.
 - (10) "Vaccination" means the act of administering any antigen in order to induce immunity; is not synonymous with immunization since vaccination does not imply success.
 - (11) "Vaccine" means a specially prepared antigen, which upon administration to a person will result in immunity.
 - (12) Written Protocol--A physician's order, standing medical order, or other order or protocol. A written protocol must be prepared, signed and dated by the physician and pharmacist and contain the following:
 - (A) the name of the individual physician authorized to prescribe drugs and responsible for authorizing the written protocol;
 - (B) the name of the individual pharmacist authorized to administer vaccines;
 - (C) the immunizations or vaccinations that may be administered by the pharmacist;
 - (D) procedures to follow, including any drugs required by the pharmacist for treatment of the patient, in the event of an emergency or severe adverse reaction following vaccine administration;
 - (E) the reporting requirements by the pharmacist to the physician issuing the written protocol, including content and time frame;
 - (F) locations at which the pharmacist may administer immunizations or vaccinations; and
 - (G) the requirement for annual review of the protocols by the physician and pharmacist.
- (c) Policies and Procedures
- (1) Pharmacists must follow a written protocol as specified in subsection (b)(12) of this section for administration of influenza vaccines and the treatment of severe adverse events following administration.
 - (2) The pharmacist administering vaccines must maintain written policies and procedures for handling and disposal of used or contaminated equipment and supplies.
 - (3) The pharmacist or pharmacist's agent must give the appropriate influenza vaccine information to the patient or legal representative with each dose of vaccine. The pharmacist must ensure that the patient or legal representative is available and has read, or has had read to them, the information provided and has had their questions answered prior to administering the vaccine.
 - (4) The pharmacist must report adverse events to the primary care provider as identified by the patient.
 - (5) The pharmacist shall not administer influenza vaccines to patients under 18 years of age.

(d) Pharmacist requirements. Pharmacists who enter into a written protocol with a physician to administer influenza vaccines shall:

- (1) hold a current provider level cardiopulmonary resuscitation (CPR) certification issued by the American Heart Association or the American Red Cross or equivalent;
- (2) successfully complete a certificate program in the administration of vaccines accredited by the Centers for Disease Control, the ACPE or a similar health authority or professional body approved by the Board;
- (3) maintain documentation of:
 - (A) completion of the initial course specified in paragraph (2) of this subsection;
 - (B) 3 hours of continuing education every 2 years beginning January 1, 2006, which are designed to maintain competency in the disease states, drugs, and administration of vaccines;
 - (C) current certification specified in paragraph (1) of this subsection;
 - (D) original written physician protocol;
 - (E) annual review and revision of original written protocol with physician;
 - (F) any problems or complications reported; and
 - (G) items specified in subsection (g) of this section.

(e) Supervising Physician responsibilities. Physicians who enter into a written protocol with a pharmacist to administer influenza vaccines shall:

- (1) be responsible for the formulation or approval and periodic review of the written protocols;
- (2) be easily accessible to the pharmacist administering the vaccines or be available through direct telecommunication for consultation, assistance, direction, and provide adequate back-up coverage; and
- (3) review written protocol with pharmacist at least annually and revise if necessary.

(f) Supervision. Pharmacists involved in the administration of immunizations or vaccinations shall be under the supervision of a physician. Physician supervision shall be considered adequate if the delegating physician:

- (1) is responsible for the formulation or approval of the physician's order, standing medical order, standing delegation order, or other order or protocol and periodically reviews the order or protocol and the services provided to a patient under the order or protocol;
- (2) is geographically located so as to be easily accessible to the pharmacist administering the immunization or vaccination;
- (3) receives, as appropriate, a periodic status report on the patient, including any problem or complication encountered; and
- (4) is available through direct telecommunication for consultation, assistance, and direction.

(g) Drugs. The following requirements pertain to drugs administered by a pharmacist:

- (1) Drugs administered by a pharmacist under the provisions of this section shall be in the legal possession of:
 - (A) a pharmacy, which shall be the pharmacy responsible for drug accountability, including the maintenance of records of administration of the immunization or vaccination; or
 - (B) a physician, who shall be responsible for drug accountability, including the maintenance of records of administration of the immunization or vaccination;
- (2) Drugs shall be transported and stored at the proper temperatures indicated for each drug;
- (3) Pharmacists while actively engaged in the administration of vaccines under written protocol, may have in their custody and control the vaccines identified in the written protocol and any other drugs listed in the written protocol to treat adverse reactions; and
- (4) After administering vaccines at a location other than a pharmacy, the pharmacist shall return all unused prescription medications to the pharmacy or physician responsible for the drugs.

(h) Record Keeping and Reporting

- (1) A pharmacist who administers any influenza vaccine shall maintain the following information, readily retrievable, in the pharmacy records regarding each administration:
 - (A) The name, address, and date of birth of the patient;
 - (B) The date of the administration;
 - (C) The administration site of injection (e.g., right arm, left leg, right upper arm);
 - (D) route of administration of the vaccine;
 - (E) The name, manufacturer, lot number, and expiration date of the vaccine;
 - (F) Dose administered;
 - (G) The name and address of the patient's primary health care provider, as identified by the patient; and
 - (H) The name or identifiable initials of the administering pharmacist.
- (2) A pharmacist who administers influenza vaccines shall document annual review with physician of written protocol in the records of the pharmacy that is in possession of the vaccines administered.

(i) Confidentiality.

- (1) The pharmacist shall comply with the privacy provisions of the federal Health Insurance Portability and Accountability Act of 1996 and any rules adopted pursuant to this act.
- (2) Any other confidentiality provisions of federal or state laws.
- (3) Violations of these rules by a pharmacist and/or supervising physician shall constitute grounds by the licensee's respective Board to initiate disciplinary action against that licensee's license.

ADJOURNMENT

This meeting was adjourned on August 30, 2004.

Robert C. Moffatt, MD
Secretary