

North Carolina Medical Board
Allied Health Committee – Agenda
January 18, 2012
Conference Room “E” – 10:00 a.m.

William Walker, MD, Chairperson, Peggy Robinson PA-C, Cheryl L. Walker-McGill, MD

Present:

Absent:

Open Session Physician Assistants

1. Revisions to PA Rules: 21 NCAC 32S.0208.1 LIMITED VOLUNTEER LICENSE and 21 NCAC 32S.0208.2 RETIRED LIMITED VOLUNTEER LICENSE (note: the person can have an inactive license).

Issue: Revise PA Rules 21 NCAC 32S.0208.1 LIMITED VOLUNTEER LICENSE and 21 NCAC 32S.0208.2 RETIRED LIMITED VOLUNTEER LICENSE (note: the person can have an inactive license) to include changes:

- Add: Submit a NPDB/HIPDB report, dated within 60 days of submission of the application
- Delete: Renewal fees

Staff Recommendation: Approve changes to PA Rules.

2. Physician Assistant Advisory Council (PAAC) 2012 Committee Members.

Issue: The North Carolina Medical Board’s Physician Assistant Advisory Council (PAAC) advises and communicates with the Board on issues affecting PA practice and regulation in the state. The PAAC does not have authority to license or discipline PAs, but it provides valuable insights to the Board’s Allied Health Committee and to the full Board. The PAAC meets once a year in July. The members of the PAAC are nominated by the Allied Health Committee and appointed by vote of the full Board for terms of two years. They may be reappointed by Board action. The PAAC’s members represent the leadership of the North Carolina Academy of Physician Assistants, the PA Section of the North Carolina Medical Society and each PA training program in North Carolina. They also include other PA and physician members chosen for their particular expertise on issues facing the Board.

Staff Recommendation: Approve the following 2012 PAAC Committee Members:

William Walker, MD, Chair, Peggy Robinson, PA, Cheryl Walker-McGill, MD, Marc Katz, PA, Katy Martinelli, PA, James Hill, PA, Robin Hunter-Buskey, PA, Douglas Hammer, MD, Julie Daniel-Yount, PA, Carolyn Pugh, PA, Lisa Shock, PA, Mike Borden, Suzanne Reich, PA - Wake Forest, Pat Dieter, PA – Duke, Ron Foster, PA - Methodist, Rosalind Becker, PA – Wingate, Patrick Carter, PA – ECU, Marcus Jimison - NCMB Staff, Lori Ann King - NCMB Staff, Katharine Kovacs - NCMB Staff, Jane Paige - NCMB Staff

Open Session NC Emergency Medical Services

1. None at present time.

Issue: None.

Staff Recommendation: None.

North Carolina Medical Board
Allied Health Committee
Anesthesiologist Assistants, Nurse Practitioners, Clinical Pharmacists Practitioners,
Perfusionists and Polysomnography Technicians
January 2012

William Walker, MD, Chair; Peggy Robinson, PA-C; Eleanor Greene, MD

1. Open Session Anesthesiologist Assistants
 - a. No Items for discussion
2. Open Session Nurse Practitioners
 - a. No Items for discussion
3. Open Session Clinical Pharmacist Practitioners
 - a. 21 NCAC 32U .0101
 - i. Summary: The rule amendment for 21 NCAC 32U .0101 which if approved by RRC would allow pharmacists with disabilities to perform vaccinations as long as a CPR-certified pharmacist or technician is present, has been published in the NC register and a public hearing will be held at the Pharmacy Board on January 9th.

Staff Recommendation: Approve the rule change.

4. Open Session Perfusionists
 - a. Open session portion of the minutes of the November PAC meeting.
 - i. Summary: The open session minutes of the November PAC meeting have been sent to the Committee members for review.

Staff Recommendation: Accept as information

- b. Appointment of a new perfusionist member to the PAC
 - i. Summary: The Medical Board appoints the perfusionist members of the Perfusionist Advisory Committee. William Hodges, CCP, LP and Gretta Evans, CCP, LP are requesting reappointment to the PAC as their current terms have expired.

Staff Recommendation: Reappoint Mr. Hodges and Ms. Evans to the Committee.

5. Open Session Polysomnographic Technologists
 - a. No items for discussion

21 NCAC 32U .0101 is proposed to be amended as follows:

21 NCAC 32U .0101 ADMINISTRATION OF VACCINES BY PHARMACISTS

(a) Purpose. The purpose of this Rule is to provide standards for pharmacists engaged in the administration of influenza, pneumococcal and zoster vaccines as authorized in G.S. 90-85.3(r) of the North Carolina Pharmacy Practice Act.

(b) Definitions. The following words and terms, when used in this Rule, shall have the following meanings, unless the context 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 physician or pharmacist.
- (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 G.S. 90-1, et seq.
- (9) "Physician" means a currently licensed M.D. or D.O. 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 may result in immunity.
- (12) Written Protocol-A physician's written 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 Subparagraph (b)(12) of this Rule for administration of influenza, pneumococcal and zoster 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, most current vaccine information regarding the purpose, risks, benefits, and contraindications of the vaccine 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 him or her, the information provided and has had his or her 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 vaccines to patients under 18 years of age.
- (6) The pharmacist shall not administer the pneumococcal or zoster vaccines to a patient unless the pharmacist first consults with the patient's primary care provider. The pharmacist shall document in the patient's profile the primary care provider's order to administer the pneumococcal or zoster vaccines. In the event the patient does not have a primary care provider, the pharmacist shall not administer the pneumococcal or zoster vaccines to the patient.
- (7) The pharmacist shall report all vaccines administered to the patient's primary care provider and report all vaccines administered to all entities as required by law, including any State registries which may be implemented in the future.

(d) Pharmacist requirements. Pharmacists who enter into a written protocol with a physician to administer 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 Subparagraph (2) of this Paragraph;
- (B) three hours of continuing education every two 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 Subparagraph (1) of this Paragraph;
- (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 Paragraph (g) of this Rule.

(4) A pharmacist who, because of physical disability, is unable to obtain a current provider level CPR certification may administer vaccines in the presence of a pharmacy technician or pharmacist who holds a current provider level CPR certification.

(e) Supervising Physician responsibilities. Pharmacists who administer vaccines shall enter into a written protocol with a supervising physician who agrees to meet the following requirements:

- (1) be responsible for the formulation or approval and periodic review of the physician's order, standing medical order, standing delegation order, or other order or written protocol and periodically review the order or protocol and the services provided to a patient under the order or protocol;
- (2) be accessible to the pharmacist administering the vaccines or be available through direct telecommunication for consultation, assistance, direction, and provide back-up coverage;
- (3) review written protocol with pharmacist at least annually and revise if necessary; and
- (4) receive a periodic status report on the patient, including any problem or complication encountered.

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

- (1) Drugs administered by a pharmacist under the provisions of this Rule 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 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.

(g) Record Keeping and Reporting.

- (1) A pharmacist who administers any 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;

- 1 (B) The date of the administration;
- 2 (C) The administration site of injection (e.g., right arm, left leg, right upper arm);
- 3 (D) Route of administration of the vaccine;
- 4 (E) The name, manufacturer, lot number, and expiration date of the vaccine;
- 5 (F) Dose administered;
- 6 (G) The name and address of the patient's primary health care provider, as identified by the
- 7 patient; and
- 8 (H) The name or identifiable initials of the administering pharmacist.

9 (2) A pharmacist who administers vaccines shall document annual review with physician of written

10 protocol in the records of the pharmacy that is in possession of the vaccines administered.

11 (h) Confidentiality.

- 12 (1) The pharmacist shall comply with the privacy provisions of the federal Health Insurance Portability
- 13 and Accountability Act of 1996 and any rules adopted pursuant to this act.
- 14 (2) The pharmacist shall comply with any other confidentiality provisions of federal or state laws.

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16 *History Note: Authority G.S. 90-85.3(r);*

17 *Emergency Adoption Eff. September 10, 2004;*

18 *Temporary Adoption Eff. December 29, 2004;*

19 *Eff. November 1, 2005;*

20 *Amended Eff. February 1, 2008;*

21 *Emergency Amendment Eff. October 9, 2009;*

22 *Temporary Amendment Eff. December 29, 2009;*

23 *Temporary Amendment Expired on October 12, 2010.*

24 *Amended Eff. March 1, 2012.*

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MINUTES

Perfusionist Advisory Committee
of the North Carolina Medical Board

November 07, 2011

**1203 Front Street
Raleigh, North Carolina**

The November 07, 2011 meeting of the Perfusionist Advisory Committee was held via conference call at the North Carolina Medical Board's (NCMB) Office, 1203 Front Street, Raleigh, NC 27609. The meeting was called to order at 5:10 p.m. by Ian Shearer, CCP, LP. Members in attendance were: Robert Kyle, DO; Gretta Evans, CCP, LP; Shikha Sinha, MSPH; Vanessa King, NP, MBA; and Betsy Gaskins-McClaine, RN, BSN, MSN-C. William Hodges, CCP, LP was absent.

Staff members present were: Mr. Marcus Jimison, Board Attorney; Mrs. Joy Cooke, Director of License Department; and Ms. Quanta Williams, Perfusionist Coordinator.

Opening Comments

Mr. Shearer read the conflict of interest statement and thanked the members for their participation in the meeting.

Approval of Minutes

The minutes from the September meeting have been reviewed by the PAC members.

Motion: A motion was made to accept the minutes from the September meeting. **Passed.**

Board Actions

The Committee reviewed the actions regarding perfusionists from the September NCMB meeting.

Licenses Issued/Converted

One provisional license and one full license have been issued or converted since the last meeting.

Closed Session

Motion: A motion was made to go into closed session to discuss matters regarding applications and other nonpublic matters. **Passed.**

Motion: A motion was made to return to open session. **Passed.**

Other Business

The Chair asked Ms. Williams to send out the 2012 schedule.

Next Meeting

January 5, 2012

Motion: A motion was made to adjourn the meeting. **Passed.**

The meeting was adjourned at 4:55 pm