

1 21 NCAC 32U .0101 is proposed to be amended as follows:

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3 **21 NCAC 32U .0101 ADMINISTRATION OF VACCINES BY PHARMACISTS**

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

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

8 (1) "ACPE" means Accreditation Council for Pharmacy Education.

9 (2) "Administer" means the direct application of a drug to the body of a patient by injection, inhalation,  
10 ingestion, or other means by:

11 (A) a pharmacist, an authorized agent under his/her supervision, or other person authorized by  
12 law; or

13 (B) the patient at the direction of a physician or pharmacist.

14 (3) "Antibody" means a protein in the blood that is produced in response to stimulation by a specific  
15 antigen. Antibodies help destroy the antigen that produced them. Antibodies against an antigen  
16 usually equate to immunity to that antigen.

17 (4) "Antigen" means a substance recognized by the body as being foreign; it results in the production of  
18 specific antibodies directed against it.

19 (5) "Board" means the North Carolina Board of Pharmacy.

20 (6) "Confidential record" means any health-related record that contains information that identifies an  
21 individual and that is maintained by a pharmacy or pharmacist such as a patient medication record,  
22 prescription drug order, or medication order.

23 (7) "Immunization" means the act of inducing antibody formation, thus leading to immunity.

24 (8) "Medical Practice Act" means G.S. 90-1, et seq.

25 (9) "Physician" means a currently licensed M.D. or D.O. with the North Carolina Medical Board who is  
26 responsible for the on-going, continuous supervision of the pharmacist pursuant to written protocols  
27 between the pharmacist and the physician.

28 (10) "Vaccination" means the act of administering any antigen in order to induce immunity; is not  
29 synonymous with immunization since vaccination does not imply success.

30 (11) "Vaccine" means a specially prepared antigen, which upon administration to a person may result in  
31 immunity.

32 (12) Written Protocol-A physician's written order, standing medical order, or other order or protocol. A  
33 written protocol must be prepared, signed and dated by the physician and pharmacist and contain the  
34 following:

35 (A) the name of the individual physician authorized to prescribe drugs and responsible for  
36 authorizing the written protocol;

37 (B) the name of the individual pharmacist authorized to administer vaccines;

- 1 (C) the immunizations or vaccinations that may be administered by the pharmacist;
- 2 (D) procedures to follow, including any drugs required by the pharmacist for treatment of the
- 3 patient, in the event of an emergency or severe adverse reaction following vaccine
- 4 administration;
- 5 (E) the reporting requirements by the pharmacist to the physician issuing the written protocol,
- 6 including content and time frame;
- 7 (F) locations at which the pharmacist may administer immunizations or vaccinations; and
- 8 (G) the requirement for annual review of the protocols by the physician and pharmacist.

9 (c) Policies and Procedures.

- 10 (1) Pharmacists must follow a written protocol as specified in Subparagraph (b)(12) of this Rule for
- 11 administration of influenza, pneumococcal and zoster vaccines and the treatment of severe adverse
- 12 events following administration.
- 13 (2) The pharmacist administering vaccines must maintain written policies and procedures for handling and
- 14 disposal of used or contaminated equipment and supplies.
- 15 (3) The pharmacist or pharmacist's agent must give the appropriate, most current vaccine information
- 16 regarding the purpose, risks, benefits, and contraindications of the vaccine to the patient or legal
- 17 representative with each dose of vaccine. The pharmacist must ensure that the patient or legal
- 18 representative is available and has read, or has had read to him or her, the information provided and
- 19 has had his or her questions answered prior to administering the vaccine.
- 20 (4) The pharmacist must report adverse events to the primary care provider as identified by the patient.
- 21 (5) The pharmacist shall not administer vaccines to patients under 18 years of age.
- 22 (6) The pharmacist shall not administer the pneumococcal or zoster vaccines to a patient unless the
- 23 pharmacist first consults with the patient's primary care provider. The pharmacist shall document in
- 24 the patient's profile the primary care provider's order to administer the pneumococcal or zoster
- 25 vaccines. In the event the patient does not have a primary care provider, the pharmacist shall not
- 26 administer the pneumococcal or zoster vaccines to the patient.
- 27 (7) The pharmacist shall report all vaccines administered to the patient's primary care provider and report
- 28 all vaccines administered to all entities as required by law, including any State registries which may be
- 29 implemented in the future.

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

31 shall:

- 32 (1) hold a current provider level cardiopulmonary resuscitation (CPR) certification issued by the
- 33 American Heart Association or the American Red Cross or equivalent;
- 34 (2) successfully complete a certificate program in the administration of vaccines accredited by the Centers
- 35 for Disease Control, the ACPE or a similar health authority or professional body approved by the
- 36 Board;
- 37 (3) maintain documentation of:

- 1 (A) completion of the initial course specified in Subparagraph (2) of this Paragraph;
- 2 (B) three hours of continuing education every two years beginning January 1, 2006, which are
- 3 designed to maintain competency in the disease states, drugs, and administration of vaccines;
- 4 (C) current certification specified in Subparagraph (1) of this Paragraph;
- 5 (D) original written physician protocol;
- 6 (E) annual review and revision of original written protocol with physician;
- 7 (F) any problems or complications reported; and
- 8 (G) items specified in Paragraph (g) of this Rule.

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

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

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

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

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

34 (g) Record Keeping and Reporting.

- 35 (1) A pharmacist who administers any vaccine shall maintain the following information, readily
- 36 retrievable, in the pharmacy records regarding each administration:
  - 37 (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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