

1 21 NCAC 46. 2507 is proposed for amendment as follows:

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3 **21 NCAC 46 .2507 ADMINISTRATION OF VACCINES BY PHARMACISTS**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10 (c) Policies and Procedures.

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

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

- 34 (1) hold a current provider level cardiopulmonary resuscitation (CPR) certification issued by the
35 American Heart Association or the American Red Cross or equivalent;

- 1 (2) successfully complete a certificate program in the administration of vaccines accredited by the
2 Centers for Disease Control, the ACPE or a similar health authority or professional body approved
3 by the Board;
- 4 (3) maintain documentation of:
 - 5 (A) completion of the initial course specified in Subparagraph (2) of this Paragraph;
 - 6 (B) three hours of continuing education every two years beginning January 1, 2006, which
7 are designed to maintain competency in the disease states, drugs, and administration of
8 vaccines;
 - 9 (C) current certification specified in Subparagraph (1) of this Paragraph;
 - 10 (D) original written physician protocol;
 - 11 (E) annual review and revision of original written protocol with physician;
 - 12 (F) any problems or complications reported; and
 - 13 (G) items specified in Paragraph (g) of this Rule.
- 14 (4) A pharmacist who, because of physical disability, is unable to obtain a current provider level CPR
15 certification may administer vaccines in the presence of a pharmacy technician or pharmacist who
16 holds a current provider level CPR certification.

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

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

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

- 28 (1) Drugs administered by a pharmacist under the provisions of this Rule shall be in the legal
29 possession of:
 - 30 (A) a pharmacy, which shall be the pharmacy responsible for drug accountability, including
31 the maintenance of records of administration of the immunization or vaccination; or
 - 32 (B) a physician, who shall be responsible for drug accountability, including the maintenance
33 of records of administration of the immunization or vaccination;
- 34 (2) Drugs shall be transported and stored at the proper temperatures indicated for each drug;
- 35 (3) Pharmacists while engaged in the administration of vaccines under written protocol, may have in
36 their custody and control the vaccines identified in the written protocol and any other drugs listed
37 in the written protocol to treat adverse reactions; and

1 (4) After administering vaccines at a location other than a pharmacy, the pharmacist shall return all
2 unused prescription medications to the pharmacy or physician responsible for the drugs.

3 (g) Record Keeping and Reporting.

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

6 (A) The name, address, and date of birth of the patient;

7 (B) The date of the administration;

8 (C) The administration site of injection (e.g., right arm, left leg, right upper arm);

9 (D) Route of administration of the vaccine;

10 (E) The name, manufacturer, lot number, and expiration date of the vaccine;

11 (F) Dose administered;

12 (G) The name and address of the patient's primary health care provider, as identified by the
13 patient; and

14 (H) The name or identifiable initials of the administering pharmacist.

15 (2) A pharmacist who administers vaccines shall document annual review with physician of written
16 protocol in the records of the pharmacy that is in possession of the vaccines administered.

17 (h) Confidentiality.

18 (1) The pharmacist shall comply with the privacy provisions of the federal Health Insurance
19 Portability and Accountability Act of 1996 and any rules adopted pursuant to this act.

20 (2) The pharmacist shall comply with any other confidentiality provisions of federal or state laws.

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22 *History Note: Authority G.S. 90-85.3; 90-85.6;*

23 *Eff. April 1, 2003;*

24 *Emergency Amendment Eff. May 11, 2004;*

25 *Temporary Amendment approved by RRC October 21, 2004;*

26 *Amended Eff. February 1, 2008; November 1, 2005; November 1, 2004;*

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

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

29 *Amended Eff. March 1, 2012.*