

1 21 NCAC 46 .2507 is amended with changes as published in 28:20 NCR 2426 as follows:

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

4 (a) An Immunizing Pharmacist shall administer only those vaccines or immunizations permitted by ~~[G.S.]~~
5 G.S. 90-85.15B and shall do so subject to all requirements of that statute and this Rule. Purpose. The purpose of
6 this Rule is to provide standards for pharmacists engaged in the administration of influenza, pneumococcal and
7 zoster vaccines as authorized in G.S. 90-85.3(r) of the North Carolina Pharmacy Practice Act.

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

10 (1) ~~—~~ "ACPE" means Accreditation Council for Pharmacy Education.

11 (2) (1) "Administer" means the direct application of a drug to the body of a patient by injection,
12 inhalation, ingestion, or other means by:

13 (A) an Immunizing Pharmacist or a Pharmacy Intern [pharmacy intern] who is under the
14 direct, in-person supervision of an Immunizing Pharmacist; a pharmacist, an authorized
15 agent under the pharmacist's supervision, or other person authorized by law; or

16 (B) the patient at the direction of either an Immunizing Pharmacist or a health care provider
17 authorized by North Carolina law to prescribe the vaccine. a physician or pharmacist.

18 (2) ~~—~~ "Immunizing Pharmacist" shall have the meaning provided in ~~[G.S.]~~ G.S. 90-85.3(i1).

19 (3) "Pharmacy Intern" [intern] shall have the meaning provided in 21 NCAC 46 .1317(28).
20 "Antibody" means a protein in the blood that is produced in response to stimulation by a specific
21 antigen. Antibodies help destroy the antigen that produced them. Antibodies against an antigen
22 usually equate to immunity to that antigen.

23 (4) "Physician" means a [currently licensed] M.D. or D.O. currently licensed with the North Carolina
24 Medical Board who is responsible for the [on-going, continuous] supervision of the Immunizing
25 Pharmacist pursuant to the Written Protocol between the Immunizing Pharmacist and the
26 Physician. [physician.] "Antigen" means a substance recognized by the body as being foreign; it
27 results in the production of specific antibodies directed against it.

28 (5) ~~—~~ "Board" means the North Carolina Board of Pharmacy.

29 (6) ~~—~~ "Confidential record" means any health related record that contains information that identifies an
30 individual and that is maintained by a pharmacy or pharmacist such as a patient medication
31 record, prescription drug order, or medication order.

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

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

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

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

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

5 ~~(5) RESERVED~~

6 ~~(6) RESERVED~~

7 ~~(7) RESERVED~~

8 ~~(8) RESERVED~~

9 ~~(9) RESERVED~~

10 ~~(10) RESERVED~~

11 ~~(11) RESERVED~~

12 (12) ~~"Written Protocol" protocol" is a document~~ means a physician's written order, standing medical
13 ~~order, or other order or protocol. A written protocol must be prepared, signed signed,~~ and dated
14 by the ~~physician~~ Physician and Immunizing Pharmacist that shall ~~pharmacist~~ and contain the
15 following:

16 (A) the name of the Physician ~~individual physician~~ authorized to prescribe drugs and
17 responsible for authorizing the Written Protocol; ~~written protocol~~;

18 (B) the name of the Immunizing Pharmacist ~~individual pharmacist~~ authorized to administer
19 vaccines;

20 (C) the immunizations or vaccinations that may be administered by the Immunizing
21 Pharmacist; ~~pharmacist~~;

22 (D) the screening questionnaires and safety procedures that shall at least include the then-
23 current minimum standard screening questionnaire and safety procedures adopted by the
24 Medical Board, the Board of [Nursing] Nursing, and the Board of Pharmacy pursuant to
25 S.L. 2013-246, s. ~~[6.]~~ 6, and available at the Board of Pharmacy's office and on its
26 website (www.ncbop.org).

27 ~~(D)~~ (E) the procedures to follow, including any drugs required by the Immunizing Pharmacist
28 pharmacist for treatment of the patient, in the event of an emergency or severe adverse
29 event reaction following vaccine administration;

30 ~~(E)~~ (F) the reporting requirements by the pharmacist Immunizing Pharmacist to the Physician,
31 physician issuing the written protocol, including content and time frame; and

32 ~~(F)~~ (G) the locations at which the pharmacist Immunizing Pharmacist may administer
33 immunizations or vaccinations. ~~vaccinations; and~~

34 ~~(G)~~ ~~the requirement for annual review of the protocols by the physician and pharmacist.~~

35 The Physician and the Immunizing Pharmacist [must] shall review the Written Protocol at least
36 annually and revise it if necessary.

37 ~~(e) 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. If 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 an equivalent certification organization;~~
- ~~(2) — successfully complete a certificate program in the administration of vaccines accredited by the Centers for Disease Control, the ACPE or a health authority or professional body approved by the Board as having a certificate program similar to the programs accredited by either the Centers for Disease Control or the ACPE;~~
- ~~(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;~~~~

1 (E) ~~annual review and revision of original written protocol with physician;~~

2 (F) ~~any problems or complications reported; and~~

3 (G) ~~items specified in Paragraph (g) of this Rule.~~

4 (c) ~~A pharmacist~~ An Immunizing Pharmacist who, because of physical disability, is unable to obtain a current
5 provider level CPR certification pursuant to ~~{G.S.} G.S. 90-85.3(i1)(1).~~ may administer vaccines in the presence of
6 a pharmacy technician or pharmacist who holds a current provider level CPR certification.

7 (d) ~~With each dose of vaccine, either the Immunizing Pharmacist or a~~ Pharmacy Intern shall ~~[pharmacy intern~~
8 ~~must] give the~~ [appropriate,] most current vaccine information regarding the purpose, risks, benefits, and
9 contraindications of the vaccine to the patient or legal representative. The Immunizing Pharmacist or Pharmacy
10 Intern ~~[pharmacy intern]~~ must ensure that the patient or legal representative has the opportunity to read, or to have
11 read to him or her, the information provided and to have any questions answered prior to administration of the
12 vaccine.

13 (e) ~~Supervising Physician responsibilities. Pharmacists who administer vaccines shall enter into a written protocol~~
14 ~~with a supervising physician who agrees~~ [The] In agreeing to serve as a supervising Physician, the Physician [must]
15 shall agree to meet the following requirements:

16 (1) be responsible for the formulation or approval and periodic review of the Written Protocol
17 ~~physician's order, standing medical order, standing delegation order, or other order or written~~
18 ~~protocol and periodically review the Written Protocol order or protocol and the services provided~~
19 ~~to patients a patient under the Written Protocol, as set out in subsection (b)(12) of this Rule;~~
20 [Protocol;] order or protocol;

21 (2) be accessible to the Immunizing Pharmacist ~~pharmacist administering the vaccines~~ or be
22 available through direct telecommunication for consultation, assistance, direction, and provide
23 back-up coverage; and

24 (3) ~~review written protocol with pharmacist at least annually and revise if necessary; and~~

25 (4) (3) receive a periodic status reports from the Immunizing Pharmacist, report on the patient, including
26 any problem problems or complications ~~complication~~ encountered.

27 (f) Drugs. The following requirements pertain to drugs administered by an Immunizing Pharmacist: ~~a pharmacist;~~

28 (1) Drugs administered by an Immunizing Pharmacist ~~a pharmacist~~ under the provisions of this Rule
29 shall be in the legal 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) the Physician, a physician, who shall be responsible for drug accountability, including
33 the maintenance 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, Immunizing Pharmacists, while engaged in the administration of vaccines under the
36 Written Protocol, ~~written protocol,~~ shall have in their custody and control the vaccines identified

1 in the ~~Written Protocol~~ ~~written protocol~~ and any other drugs listed in the ~~Written Protocol~~ ~~written~~
2 ~~protocol~~ to treat adverse ~~events; reactions;~~ and

- 3 (4) After administering vaccines at a location other than a pharmacy, the ~~pharmacist~~ Immunizing
4 Pharmacist shall return all unused prescription medications to the pharmacy or Physician
5 physician responsible for the drugs.

6 (g) Record Keeping and Reporting.

- 7 (1) ~~A pharmacist who administers any vaccine~~ An Immunizing Pharmacist shall maintain the
8 following information, readily retrievable, in the pharmacy records in accordance with the
9 applicable rules and statute regarding each administration:

- 10 (A) The the name, address, and date of birth of the patient;
11 (B) The the date of the administration;
12 (C) The the administration site of injection (~~e.g., (e.g.,~~ right arm, left leg, right upper arm);
13 (D) Route route of administration of the vaccine;
14 (E) The the name, manufacturer, lot number, and expiration date of the vaccine;
15 (F) Dose dose administered;
16 (G) The the name and address of the patient's primary health care provider, as identified by
17 the patient; and
18 (H) The the name or identifiable initials of the Immunizing Pharmacist, ~~administering~~
19 ~~pharmacist~~.

- 20 (2) ~~A pharmacist who administers vaccines~~ An Immunizing Pharmacist shall document the annual
21 review with the Physician ~~physician~~ of the Written Protocol as required in this Rule. ~~written~~
22 ~~protocol in the records of the pharmacy that is in possession of the vaccines administered.~~

- 23 (3) ~~An Immunizing Pharmacist~~ [must] shall report adverse events associated with administration of a
24 vaccine to either the prescriber, when administering a vaccine pursuant to [G.S.] G.S. 90-
25 85.15B(a), or the patient's primary care provider, if the patient identifies one, when administering
26 a vaccine pursuant to G.S. 90-85.15B(b).

27 (h) ~~Confidentiality.~~ The Immunizing Pharmacist [must] shall maintain written policies and procedures for
28 handling and disposal of used or contaminated equipment and supplies.

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

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

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33 *History Note:* Authority G.S. 90-85.3; 90-85.6; 90-85.15B;
34 Eff. April 1, 2003;
35 Emergency Amendment Eff. May 11, 2004;
36 Temporary Amendment approved by RRC October 21, 2004;
37 Amended Eff. February 1, 2008; November 1, 2005; November 1, 2004;

- 1 *Emergency Amendment Eff. October 9, 2009;*
- 2 *Temporary Amendment Eff. December 29, 2009;*
- 3 *Amended Eff. September 1, 2014; March 1, 2012.*