

21 NCAC 46 .2507 ADMINISTRATION OF VACCINES BY PHARMACISTS

(a) An Immunizing Pharmacist shall administer only those vaccines or immunizations permitted by G.S. 90-85.15B and shall do so subject to all requirements of that statute and this Rule.

(b) The following words and terms, when used in this Rule, have the following meanings:

- (1) "Administer" means the direct application of a drug to the body of a patient by injection, inhalation, ingestion, or other means by:
 - (A) an Immunizing Pharmacist;
 - (B) a Pharmacy Intern or registered pharmacy technician who is under the supervision of an Immunizing Pharmacist; or
 - (C) the patient at the direction and under the direct, in-person supervision of either an Immunizing Pharmacist or a health care provider authorized by North Carolina law to prescribe the vaccine.
- (2) "Immunizing Pharmacist" shall have the meaning provided in G.S. 90-85.3(i1).
- (3) "Immunizing Pharmacy Personnel" means an Immunizing Pharmacist, or a Pharmacy Intern or a registered pharmacy technician who administers vaccines under the supervision of an Immunizing Pharmacist.
- (4) "Pharmacy Intern" shall have the meaning provided in 21 NCAC 46 .1317(16).
- (5) "Physician" means an M.D. or D.O. currently licensed with the North Carolina Medical Board who is responsible for the supervision of the Immunizing Pharmacist pursuant to the Written Protocol between the Immunizing Pharmacist and the Physician.
- (6) RESERVED
- (7) RESERVED
- (8) RESERVED
- (9) RESERVED
- (10) RESERVED
- (11) RESERVED
- (12) "Written Protocol" is a document prepared, signed, and dated by the Physician and Immunizing Pharmacist that shall contain the following:
 - (A) the name of the Physician responsible for authorizing the Written Protocol;
 - (B) the name of the Immunizing Pharmacist authorized to administer vaccines;
 - (C) the immunizations or vaccinations that may be administered by the Immunizing Pharmacist;
 - (D) the screening questionnaires and safety procedures that shall at least include the then-current minimum standard screening questionnaire and safety procedures adopted by the Medical Board, the Board of Nursing, and the Board of Pharmacy pursuant to S.L. 2013-246, s. 6, and available at the Board of Pharmacy's office and on its website (www.ncbop.org).
 - (E) the procedures to follow, including any drugs required by the Immunizing Pharmacist for treatment of the patient, in the event of an emergency or adverse event following vaccine administration;
 - (F) the reporting requirements by the Immunizing Pharmacist to the Physician, including content and time frame; and
 - (G) the locations at which the Immunizing Pharmacist may administer immunizations or vaccinations.

The Physician and the Immunizing Pharmacist shall review the Written Protocol at least annually and revise it if necessary.

(c) A registered pharmacy technician may administer those vaccines or immunizations permitted by G.S. 90-85.15B on behalf of an Immunizing Pharmacist, if the registered pharmacy technician does the following:

- (1) Completes a practical training program that is approved by the Accreditation Council of Pharmacy Education;
- (2) Holds a current basic CPR certification;
- (3) Notifies the North Carolina Board of Pharmacy of immunizing pharmacy technician status;
- (4) Is supervised by an Immunizing Pharmacist who is responsible for ensuring compliance with all legal requirements for vaccinations administered by a registered pharmacy technician under this Rule;

- (5) Either (i) has an Immunizing Pharmacist on site and readily available to assist as needed, or (ii) has another licensed health care provider authorized to administer vaccines on site and readily available to assist as needed and has a supervising pharmacist readily available by phone or other telecommunications method for consultation as needed;
 - (6) Has the Immunizing Pharmacist or other health care provider who is present under Subparagraph (5) of this Paragraph review the patient's vaccine registry or other vaccination records and the screening questionnaire before the pharmacy technician administers the vaccine;
 - (7) Makes an offer of counseling in compliance with Rule .2504 of this Section; and
 - (8) Maintains documentation of three hours of immunization-related continuing education approved by the Accreditation Council for Pharmacy Education every two years.
- (d) Immunizing Pharmacy Personnel who, because of physical disability, are unable to obtain a current CPR certification pursuant to G.S. 90-85.3(i1)(1), may administer vaccines in the presence of a pharmacy technician, Pharmacy Intern, or pharmacist who holds a current provider level CPR certification.
- (e) With each dose of vaccine, the Immunizing Pharmacy Personnel shall give the most current vaccine information regarding the purpose, risks, benefits, and contraindications of the vaccine to the patient or legal representative. The Immunizing Pharmacy Personnel must ensure that the patient or legal representative has the opportunity to read, or to have read to him or her, the information provided and to have any questions answered prior to administration of the vaccine.
- (f) In agreeing to serve as a supervising Physician, the Physician shall agree to meet the following requirements:
- (1) be responsible for the formulation or approval of the Written Protocol and review the Written Protocol and the services provided to patients under the Written Protocol, as set out in Subparagraph (b)(12) of this Rule;
 - (2) be accessible to the Immunizing Pharmacist or be available through direct telecommunication for consultation, assistance, direction, and provide back-up coverage; and
 - (3) receive periodic status reports from the Immunizing Pharmacist, including any problems or complications encountered.
- (g) The following requirements pertain to drugs administered by Immunizing Pharmacy Personnel:
- (1) Drugs administered 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) the 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) Immunizing Pharmacy Personnel, while engaged in the administration of vaccines under the Written Protocol, shall 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 events; and
 - (4) After administering vaccines at a location other than a pharmacy, the Immunizing Pharmacy Personnel shall return all unused prescription medications to the pharmacy or Physician responsible for the drugs.
- (h) Record Keeping and Reporting.
- (1) An Immunizing Pharmacist shall maintain the following information, readily retrievable, in the pharmacy records in accordance with the applicable rules and statute 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 Immunizing Pharmacist.
 - (2) An Immunizing Pharmacist shall document the annual review with the Physician of the Written Protocol as required in this Rule.
 - (3) An Immunizing Pharmacist shall report adverse events associated with administration of a vaccine to either the prescriber, when administering a vaccine pursuant to G.S. 90-85.15B(a), or the

patient's primary care provider, if the patient identifies one, when administering a vaccine pursuant to G.S. 90-85.15B(b).

- (i) The Immunizing Pharmacist shall maintain written policies and procedures for handling and disposal of used or contaminated equipment and supplies.
- (j) The Immunizing Pharmacist shall comply with Rule .1820 of this Chapter in the practice of pharmacy pursuant to this Rule.

History Note: Authority G.S. 90-85.3; 90-85.6; 90-85.15B; S.L. 2021-110, s. 4.(a) and (b); Eff. April 1, 2003; Emergency Amendment Eff. May 11, 2004; Temporary Amendment approved by RRC October 21, 2004; Amended Eff. February 1, 2008; November 1, 2005; November 1, 2004; Emergency Amendment Eff. October 9, 2009; Temporary Amendment Eff. December 29, 2009; Amended Eff. September 1, 2014; March 1, 2012; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017; Amended Eff. March 1, 2023; July 1, 2022; June 1, 2020.