REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina Board of Pharmacy

RULE CITATION: 21 NCAC 46 .2507

DEADLINE FOR RECEIPT: Thursday, August 14, 2014

***NOTE WELL:* This request when viewed on computer extends several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this rule prior to the Commission's next meeting. The Commission has not yet reviewed this rule and therefore there has not been a determination as to whether the rule will be approved. You may call this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made:

In (b) is "definitions." necessary? It appears as though it is not for consistency purposes as you have deleted introductions elsewhere throughout this Rule (see (a), (e), and (h)).

In (b), when could the context indicate otherwise? The phrase "unless the context indicates otherwise" has the potential to create some ambiguity and seems as though it may be unnecessary.

In (b)(1)(B) and (g)(1)(G), you have used "health care provider" while you have used "Physician" elsewhere in the rule. Is there a reason that these terms are inconsistent? If not, please make them consistent.

In (b)(2) and throughout the Rule, you have capitalized "Immunizing Pharmacist"; however, the Statute referenced (G.S. 90-85.3(i1)) does not.

In (b)(3), "Pharmacy intern" is capitalized in the referenced Rule.

In (b)(4), delete or define "on-going, continuous."

In (b)(4), you have not capitalized "physician"; however, you have capitalized "physician" elsewhere in the Rule. Please be consistent in your capitalization of "Immunizing Pharmacist, Pharmacy Intern" and "Physician" throughout the Rule. I would recommend using the capitalization used in statute.

Why is it necessary to Reserve (b)(5) through (b)(11)? I understand that you may want to engage in future rule-making; however, reserving is not necessary to do so.

In (b)(12) your capitalization of "Written protocol" is inconsistent throughout the Rule. Elsewhere, you have capitalized both words.

Amber Cronk May
Commission Counsel
July 31, 2014

In (b)(12), how does a pharmacy intern come into play if he or she is administering the drug? If a pharmacy intern is administering the drug, does the written protocol need to include that possibility?

In (b)(12), line 13, please add a comma in between "signed" and "and dated."

In (b)(12)(D), please delete "at least." Please also add a comma in between "Board of Nursing" and "the Board of Pharmacy.

In (b)(12)(D), where can the "then-current minimum standard screen questionnaire and safety procedures" be found? Are these available on each of the Board's websites (or at least yours?)

In (b)(12), please change "must" to "shall." Also, when would it be necessary for the written protocol to be revised? Only when there is change in the items listed? Are there any other circumstances that would necessitate a revision?

In (c), where is it required that a pharmacist have CPR certification? Is this set out elsewhere in rule or statute?

In (d), please change "must" to "shall." Also, what is "appropriate, most current vaccine information…" it appears that "appropriate" is unnecessary.

In (e), please change "must" to "shall." Also, under what circumstances must the physician agree to meet the requirements? In order to be a supervising physician of the pharmacist?

In (e)(1), should "periodically" be "annually" as required in (b)(12)?

In (e)(2), when is the physician required to be accessible? Is it only when the immunizing pharmacist is providing immunizations or are they required to be accessible 24 hours a day, 7 days a week?

In (e)(3), what does "periodic" mean? Are these the same reports that the pharmacist is required to provide in (g)(3) of this Rule? If so, there does not appear to be a requirement of "periodic" notification in (g)(3). It is unclear when or how often the pharmacist shall report these to the physician? Is it every time an adverse event occurs?

In (f), is "drugs." necessary? It appears as though it is not for consistency purposes as you have deleted introductions elsewhere throughout this Rule (see (a), (e), and (h)).

In (g), is "record keeping and reporting." necessary? It appears as though it is not for consistency purposes as you have deleted introductions elsewhere throughout this Rule (see (a), (e), and (h)). This would create a need to change (1) to (g), etc.

In (g)(1), what do you mean by "readily retrievable"? Can this be done electronically or is a hard copy necessary? Is there another rule or statute that sets forth requirements regarding records?

The list in (g)(1) all begin with capital letters; however, the list in (b)(12) all begin with lower-case. Please be consistent (we prefer lower-case).

Are adverse events referenced in (g)(3) required to be kept in the records referenced in (g)(1). If so, that requirement is not currently listed.

In (g)(3), please change "must" to "shall."

Also, in (g)(3), you reference "adverse events" while you referenced "severe adverse reactions" in (b)(12)(E). Is the pharmacist required to report all adverse events, including minor ones? The use of "adverse events", "severe adverse reactions, and "adverse reactions" in (f)(3) are inconsistent. Was this intentional in that they have different meanings?

In (h), please change "must" to "shall." Also, are there additional guidelines set forth in rule or statute?

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Of course, this will also require conforming changes to the attached copies of the rule. Please check to see that this paperwork is in order and is returned along with the revised rule.

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

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. ~~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, have the following meanings, unless the context indicates otherwise.

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

~~(2)~~ (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 or a pharmacy intern who is under the direct, in-person supervision of an Immunizing Pharmacist; ~~a pharmacist, an authorized agent under the pharmacist's supervision, or other person authorized by law;~~ or

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

(2) "Immunizing Pharmacist" shall have the meaning provided in G..S. 90-85.3(i1).

(3) "Pharmacy intern" shall have the meaning provided in 21 NCAC 46 .1317(28). ~~"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) "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 Immunizing Pharmacist pursuant to the Written Protocol between the Immunizing Pharmacist and the physician. ~~"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.~~

(5) RESERVED

(6) RESERVED

(7) RESERVED

(8) RESERVED

(9) RESERVED

(10) RESERVED

(11) RESERVED

(12) "Written protocol" is a document ~~means 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~~ Physician and Immunizing Pharmacist that shall ~~pharmacist and~~ contain the following:

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

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

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

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

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

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

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

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

~~(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. 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;

~~(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.~~

~~A pharmacist~~ An Immunizing 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.

With each dose of vaccine, either the Immunizing Pharmacist or a pharmacy intern must give the appropriate, most current vaccine information regarding the purpose, risks, benefits, and contraindications of the vaccine to the patient or legal representative. The Immunizing Pharmacist or pharmacy intern 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.

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

(1) be responsible for the formulation or approval and periodic review of the Written Protocol ~~physician's order, standing medical order, standing delegation order, or other order or written protocol~~ and periodically review the Written Protocol ~~order or protocol~~ and the services provided to patients ~~a patient~~ under the Written Protocol; ~~order or protocol;~~

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

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

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

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

(1) Drugs administered by an Immunizing Pharmacist ~~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,~~ Immunizing Pharmacists, while engaged in the administration of vaccines under the Written Protocol, ~~written protocol,~~ shall have in their custody and control the vaccines identified in the Written Protocol ~~written protocol~~ and any other drugs listed in the Written Protocol ~~written protocol~~ to treat adverse reactions; and

(4) After administering vaccines at a location other than a pharmacy, the ~~pharmacist~~ Immunizing 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~~ An Immunizing Pharmacist 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;

(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. ~~administering pharmacist.~~

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

(3) An Immunizing Pharmacist must 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).

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

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

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

History Note: *Authority G.S. 90-85.3; 90-85.6; 90-85.15B;*
Eff. April 1, 2003;
Emergency Amendment Eff. May 11, 2004;
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Emergency Amendment Eff. October 9, 2009;
Temporary Amendment Eff. December 29, 2009;

Amended Eff. September 1, 2014; March 1, 2012.