REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: North Carolina Board of Pharmacy

RULE CITATION: 21 NCAC 46 .1820

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

***PLEASE NOTE:* This request may extend to 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 email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

On lines 4-5, please consider conforming the incorporation by reference to our usual style, which uses "hereby incorporated" and states whether "all subsequent amendments or editions" are included.

Also, I suggest swapping the final sentence regarding the availability of the Code with the second sentence, so that the incorporation by reference is contiguous.

Finally, because G.S. 150B-21.6 requires the agency to disclose the cost of the material (which here is free), please state that the Code is available online, free of charge.

On line 5, to be clear, it is the Board who is determining that conduct contrary to the Code is unprofessional, not the American Pharmacist Association?

In your History Note, there are extra spaces between the hyphens and the section numbers for 90-85.22 and 90-85.44.

Also in the History Note, I think you need a reference to G.S. 90-85.38, for disciplinary authority.

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

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

21 NCAC 46 .1820 is adopted as published in 36:16 NCR 1390 as follows:

21 NCAC 46 .1820 CODE OF ETHICS

All pharmacists must comply with the American Pharmacist Association Code of Ethics, which is incorporated herein by reference, along with all amendments to that Code of Ethics. Any contrary conduct is unprofessional conduct under G.S. 90-85.38. A copy of the Code of Ethics is available on the Board's website at http://ncbop.org/lawandrules.htm.

History Note: *Authority G.S. 90-85.3A; 90-85.6; 90-85.15A; 90-85.15B; 90- 85.22; 90-85.26; 90-85.26A; 90-85.32; 90-85.33; 90-85.34; 90- 85.44; S.L. 2021-110, s. 4.(a);*
Eff. July 1, 2022.

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: North Carolina Board of Pharmacy

RULE CITATION: 21 NCAC 46 .2507

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

***PLEASE NOTE:* This request may extend to 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 email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

In (b), line 7, I take it you are using "direct" to mirror the statutory language in G.S. 90-85.3(a)?

In (b)(1), line 8, what is "direct" here? Does your regulated public know?

In (b)(1)(A), lines 9-10, I think it would aid clarity if you broke subparagraph (A) into separate subparagraphs, such as suggested below:

(A) an Immunizing Pharmacist;
(B) a Pharmacy Intern or a registered pharmacy technician who is under the supervision of an Immunizing Pharmacist; or
~~(B)~~(C) the patient at the direction of…

In (c)(7), p.2, lines 26-27, would it change the meaning to simplify this sentence to say: "Makes an offer of counseling to the patient in compliance with Rule .2504 of this Section"?

In (c)(8), lines 28-29, what does "designed to maintain competency" mean? Who decides what CE courses/topics meet this definition? Are these the same courses required by 90-85.15B(b1)?

In (d), line 32, add the oxford comma after "Pharmacy Intern".

In (g)(1), p.3, line 10, delete "by" following "administered".

In (g)(1), line 11, what is "legal possession"? Does your regulated public know?

In (h)(1), line 24, what is "readily" retrievable? Does your regulated public know?

In (h)(1), line 25, what are the "applicable rules and statute"? Does your regulated public know?

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

In (i), p.4, lines 5-6, I understand the Immunizing Pharmacist will maintain the policies, but will he or she also write them or is there a set of policies that he or she will use?

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

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

21 NCAC 46 .2507 is amended as published in 36:16 NCR 1390 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.

(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 or a Pharmacy Intern or registered pharmacy technician who is under the ~~direct, in person~~ supervision of an Immunizing Pharmacist; 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.

(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.

~~(3)~~(4) "Pharmacy Intern" shall have the meaning provided in 21 NCAC 46 .1317(29).

~~(4)~~(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 to the patient, which offer to counsel and any counseling should comply with Rule .2504 of this Section; and

(8) Maintains documentation of three hours of continuing education every two years, designed to maintain competency in vaccine administration.

~~(c)~~(d) ~~An~~ Immunizing Pharmacy Personnel ~~Pharmacist~~ who, because of physical disability, ~~is~~ are unable to obtain a current ~~provider level~~ CPR certification pursuant to G.S. 90-85.3(i1)(1), may administer vaccines in the presence of a pharmacy technician, Pharmacy Intern ~~technician~~ or pharmacist who holds a current provider level CPR certification.

~~(d)~~(e) With each dose of vaccine, ~~either~~ the Immunizing Pharmacy Personnel ~~Pharmacist or a Pharmacy Intern~~ 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 ~~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)~~(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.

~~(f)~~(g) The following requirements pertain to drugs administered by ~~an~~ Immunizing Pharmacy Personnel: ~~Pharmacist~~:

(1) Drugs administered by ~~an Immunizing 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) 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, ~~Pharmacists,~~ 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 ~~Pharmacist~~ shall return all unused prescription medications to the pharmacy or Physician responsible for the drugs.

~~(g)~~(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).

~~(h)~~(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. June 1, ~~2020.~~ 2020; July 1, 2022.

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: North Carolina Board of Pharmacy

RULE CITATION: 21 NCAC 46 .2514

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

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In reviewing this Rule, the staff recommends the following changes be made:

In (b), line 7, I take it you are using "direct" to mirror the statutory language in G.S. 90-85.3(a)?

In (b)(1), line 8, what is "direct" here? Does your regulated public know?

In (b)(1), lines 8-9, I think it would aid clarity if you broke subparagraph (1) into separate subparagraphs, such as suggested below:

(1) an Immunizing Pharmacist;
(2) a Pharmacy Intern or a registered pharmacy technician who is under the supervision of an Immunizing Pharmacist; or
~~(2)~~(3) the patient at the direction of…

In (f)(1), line 29, what is "legal possession"? Does your regulated public know?

In (g)(1), p.2, line 7, what is "readily" retrievable? Does your regulated public know?

In (g)(1), line 8, what are the "applicable rules and statute"? Does your regulated public know?

In (h), lines 20-21, I understand the Immunizing Pharmacist will maintain the policies, but will he or she also write them or is there a set of policies that he or she will use?

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

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

21 NCAC 46 .2514 is adopted as published in 36:16 NCR 1393 as follows:

21 NCAC 46 .2514 ADMINISTRATION OF LONG-ACTING INJECTABLES

(a) A "long-acting injectable" is drug product formulated to produce sustained release and gradual absorption of the active pharmaceutical ingredient over an extended period of time after administration by subcutaneous or intramuscular injection.

(b) "Administer" means the direct application of a drug to the body of a patient by injection by:

(1) an Immunizing Pharmacist or a pharmacy intern who is under the direct, in-person supervision of an Immunizing Pharmacist; or

(2) the patient at the direction of either an Immunizing Pharmacist or a health care provider authorized by North Carolina law to prescribe the long-acting injectable.

(c) In order to administer long-acting injectables, an Immunizing Pharmacist must:

(1) satisfy all requirements to be an "Immunizing Pharmacist" under G.S. 90-85.3(i1);

(2) document training on administering long-acting injectables both subcutaneously and intramuscularly. This training may include a program accredited by the American Council on Pharmaceutical Education (ACPE) or the North Carolina Association of Pharmacists, curriculum based programs from an ACPE-accredited school of pharmacy, state or local health department programs, or training by a health care practitioner with experience in administering long-acting injectables;

(3) notify the Board of the status as both an Immunizing Pharmacist and a pharmacist who administers long-acting injectables; and

(4) administer long-acting injectables in accordance with G.S. 90-85.15B, as well as all other pertinent State and federal laws and regulations (including but not limited to U.S. Food and Drug Administration Risk Evaluation and Mitigation Strategies).

(d) An Immunizing Pharmacist who, because of physical disability, is unable to obtain a current provider level CPR certification pursuant to G.S. 90-85.3(i1)(1), may administer long-acting injectables in the presence of a pharmacy technician or pharmacist who holds a current provider level CPR certification.

(e) Before each administration of a long-acting injectable, the Immunizing Pharmacist must personally and affirmatively conduct patient counseling that complies with Rule .2504 of this Chapter.

(f) The following requirements pertain to long-acting injectables administered by an Immunizing Pharmacist:

(1) Drugs administered by an Immunizing 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 long-acting injectable; or

(B) a prescriber, who shall be responsible for drug accountability, including the maintenance of records of administration of the long-acting injectable.

(2) Drugs shall be transported and stored at the proper temperatures indicated for each drug.

(3) Immunizing Pharmacists, while engaged in the administration of long-acting injectables, shall have in their custody and control drugs needed to treat adverse events.

(4) After administering long-acting injectables at a location other than a pharmacy, the Immunizing Pharmacist shall return all unused prescription medications to the pharmacy or prescriber responsible for the drugs.

(g) 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 of a long-acting injectable:

(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 drug;

(E) the name, manufacturer, lot number, and expiration date of the drug;

(F) dose administered;

(G) the name and address of the prescriber; and

(H) the name or identifiable initials of the Immunizing Pharmacist.

(2) An Immunizing Pharmacist shall report to the prescriber adverse events associated with administration of a long-acting injectable.

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

History Note: *Authority G.S. 90-85.3; 90-85.6; 90-85.15B;*
Eff. July 1, 2022.