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

AGENCY: North Carolina Medical Board

RULE CITATION: 21 NCAC 32A .0112

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 (c)(5), line 17, would it change the meaning to say "…disciplinary or denial hearing before the Board…"?

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 32A .0112 is proposed for adoption as follows:

21 NCAC 32A .0112 DISPOSITION OF REQUEST

(a) Upon receipt of a Request for Declaratory Ruling, the Board shall determine whether a ruling is appropriate under the facts stated.

(b) When the Board determines that the issuance of a declaratory ruling is inappropriate, the Board shall notify, in writing, the person requesting the ruling, stating the reasons for the denial of the request.

(c) The Board shall decline to issue a declaratory ruling where:

(1) there has been a similar controlling factual determination made by the Board in a contested case;

(2) the rule-making record shows that the factual issues raised by the request were specifically considered prior to adoption of the rule; ~~or~~

(3) the subject-matter of the request is involved in pending litigation in any state or federal court in North Carolina;

(4) the subject-matter of the request involves matters which are currently being investigated by the Board;

(5) the subject matter of the request involves matters which are currently being adjudicated in a noticed disciplinary or denial hearing heard by the Board or the Office of Administrative Hearings; or

~~(4)~~(6) the petitioner fails to show that the circumstances are so changed since the adoption of the statute or rule that a ruling is warranted.

History Note: *Authority G.S. 150B-4;*
Eff. February 1, 2007;
Pursuant to G.S. 150B-21.3A rule is necessary without substantive public interest Eff. March 1, 2016.

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

AGENCY: North Carolina Medical Board

RULE CITATION: 21 NCAC 32U .0101

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 your History Note, please cite to SL 2021-110.

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 32U .0101 is amended as published in 36:17 NCR page 1440-1442 as follows:

SUBCHAPTER 32U - PHARMACISTS VACCINATIONS AND ADMINISTRATION OF LONG-ACTING INJECTABLES

SECTION .0100 - PHARMACISTS VACCINATIONS AND ADMINSTRATION OF LONG-ACTING INJECTABLES

21 NCAC 32U .0101 ADMINISTRATION OF VACCINES BY PHARMACISTS

Pharmacist personnel may administer vaccines in accordance with 21 NCAC 46 .2507.

~~(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 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) "Pharmacy Intern" shall have the meaning provided in 21 NCAC 46 .1317(28).~~

~~(4) "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.~~

~~(5) RESERVED~~

~~(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 North Carolina Medical Board's office and on its website (www.ncmedboard.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) 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 vaccines in the presence of a pharmacy technician or pharmacist who holds a current provider level CPR certification.

(d) With each dose of vaccine, either the Immunizing 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 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) 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 a periodic status reports from the Immunizing Pharmacist, including any problems or complications encountered.

(f) The following requirements pertain to drugs 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 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 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 Pharmacist shall return all unused prescription medications to the pharmacy or Physician 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:~~

~~(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) 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(r); 90-85.15B;*
Emergency Adoption Eff. September 10, 2004;
Temporary Adoption Eff. December 29, 2004;
Eff. November 1, 2005;
Amended Eff. February 1, 2008;
Emergency Amendment Eff. October 9, 2009;
Temporary Amendment Eff. December 29, 2009;
Temporary Amendment Expired on October 12, 2010;
Amended Eff. July 1, 2022; September 1, 2014; March 1, 2012;
Pursuant to G.S. 150B-21.3A rule is necessary without substantive public interest Eff. March 1, 2016.

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

AGENCY: North Carolina Medical Board

RULE CITATION: 21 NCAC 32U .0102

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 your History Note, please cite to G.S. 90-85.15B.

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 32U .0102 is adopted, with changes, as published im 35:17 NCR pages 1440 - 1442 as follows:

21 NCAC 32U .0102 ADMINISRATION OF ~~[LONE-ACTING]~~ LONG-ACTING INJECTABLES

Pharmacists may administer long-acting injectables in accordance with 21 NCAC 46 .2514.

History Note: Authority SL 2021-110;
Eff. July 1, 2022.