



NOTICE OF TEXT

[Authority G.S. 150B-21.2(c)]

OAH USE ONLY

VOLUME:

ISSUE:

CHECK APPROPRIATE BOX:

Notice with a scheduled hearing

Notice without a scheduled hearing

Republication of text. Complete the following cite for the volume and issue of previous publication, as well as blocks 1 - 4 and 7 - 14. If a hearing is scheduled, complete block 5.

Previous publication of text was published in Volume: Issue:

1. Rule-Making Agency: [Medical Board](#)

2. Link to agency website pursuant to G.S. 150B-19.1(c): www.ncmedboard.org/about_the_board/rule_changes

3. Proposed Action -- Check the appropriate box(es) and list rule citation(s) beside proposed action:

ADOPTION: [21 NCAC 32U .0102](#)

AMENDMENT: [21 NCAC 32U .0101](#)

REPEAL:

READOPTION with substantive changes:

READOPTION without substantive changes:

REPEAL through READOPTION:

4. Proposed effective date: [07/01/2022](#)

5. Is a public hearing planned? [Yes](#)

If yes:

Date

Time

Location

[04/28/2022](#) [10:00 am](#)

The public hearing will be held remotely. The public may participate on Teams at <https://tinyurl.com/2p8czkmb> or may call 336-604-5350, conference ID 232 964 29#

6. If no public hearing is scheduled, provide instructions on how to demand a public hearing:

7. Explain Reason For Proposed Rule(s):

21 NCAC 32U .0101: Session Law 2021-110 required the Board of Pharmacy and the Medical Board to adopt “a statement of ethics for immunizing pharmacists.” Moreover, Session Law 2021-110 adopted “unprofessional conduct” as a new ground of discipline for pharmacists (and, by extension, pharmacies) in G.S. 90-85.38. The Boards have jointly proposed adoption of the American Pharmacists Association Code of Ethics to define professional conduct, including but not limited to that conduct by immunizing pharmacists. This reflects an approach taken by numerous licensing boards in adopting an established industry set of conduct standards as reflecting appropriate professional practice. Proposed new rule 21 NCAC 46 .1820 would adopt that code of ethics by reference, and the amendments to Rule .2507 would refer to that rule as specifically governing pharmacists’ immunization activities. The Medical Board has proposed amending 21 NCAC 32U .0101 to effectively adopt the amendments to Rule .2507 by reference (and also thereby the application of new Rule .1820 to immunization).

21 NCAC 32U .0102: Session Law 2021-3, Section 2.9.(a), permits “immunizing pharmacists” (as defined by statute) to administer long-acting injectable medications to adults pursuant to prescription. The law became effective on October 1, 2021, and the Board of Pharmacy adopted a temporary rule (21 NCAC 46 .2514) to implement the section, as permitted by the statute. Because of the placement of the longacting injectable authority in the “immunizing pharmacist” statute (90-85.15B), a permanent rule governing the administration of these drugs must be approved by both the Board of Pharmacy and the Medical Board. The Board of Pharmacy has proposed adoption of a permanent version of Rule .2514. The proposed rule would put appropriate standards in place for training, recordkeeping and other requirements needed to ensure that the drugs are administered with adequate protection of the public health, safety, and welfare. The requirements in the proposed rule are largely imported from 21 NCAC 46 .2507, which governs immunizing pharmacist administration of vaccines, so that the regulated pharmacists will already be familiar with these requirements. Moreover, the proposed permanent rule does not vary in any substantial way from the temporary rule that has been operating without any known incident since October 1, 2021. The Medical Board has proposed a new rule (21 NCAC 32U .0102) that would adopt proposed permanent Rule .2514 by reference.

8. Procedure for Subjecting a Proposed Rule to Legislative Review: If an objection is not resolved prior to the adoption of the rule, a person may also submit written objections to the Rules Review Commission. If the Rules Review Commission receives written and signed objections in accordance with G.S. 150B-21.3(b2) from 10 or more persons clearly requesting review by the legislature and the Rules Review Commission approves the rule, the rule will become effective as provided in G.S. 150B-21.3(b1). The Commission will receive written objections until 5:00 p.m. on the day following the day the Commission approves the rule. The Commission will receive those objections by mail, delivery service, hand delivery, or email. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 984-236-1850.

Rule(s) is automatically subject to legislative review. Cite statutory reference:

9. The person to whom written comments may be submitted on the proposed rule(s):

Name: [Wanda Long](#)
Address: [P.O. Box 20007](#)
[Raleigh, NC 27619-0007](#)
Phone (optional):
Fax (optional):
EMail (optional) rules@ncmedboard.org

10. Comment Period Ends: [05/02/2022](#)

11. Fiscal impact. Does any rule or combination of rules in this notice create an economic impact? Check all that apply.

[No fiscal note required](#)

12. Rule-making Coordinator:

Name: [Wanda Long](#)
[919-326-1109 Ext. 212](#)
wanda.long@ncmedboard.org

Agency contact, if any:

Name: [Marcus Jimison](#)
Phone: [919.326.1109 ext 226](#)
Email: marcus.jimison@ncmedboard.org

13. The Agency formally proposed the text of this rule(s) on

Date: [01/28/2022](#)

1 21 NCAC 32U .0101 is proposed for amendment as follows:

2
3 **SUBCHAPTER 32U - PHARMACISTS VACCINATIONS AND ADMINISTRATION OF LONG-ACTING**
4 **INJECTABLES**

5
6 **SECTION .0100 - PHARMACISTS VACCINATIONS AND ADMINISTRATION OF LONG-ACTING**
7 **INJECTABLES**

8
9 **21 NCAC 32U .0101 ADMINISTRATION OF VACCINES BY PHARMACISTS**

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

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

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

14 (1) ~~"Administer" means the direct application of a drug to the body of a patient by injection, inhalation,~~
15 ~~ingestion, or other means by:~~

16 (A) ~~an Immunizing Pharmacist or a Pharmacy Intern who is under the direct, in-person~~
17 ~~supervision of an Immunizing Pharmacist; or~~

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

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

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

22 (4) ~~"Physician" means an M.D. or D.O. currently licensed with the North Carolina Medical Board who~~
23 ~~is responsible for the supervision of the Immunizing Pharmacist pursuant to the Written Protocol~~
24 ~~between the Immunizing Pharmacist and the Physician.~~

25 (5) ~~RESERVED~~

26 (6) ~~RESERVED~~

27 (7) ~~RESERVED~~

28 (8) ~~RESERVED~~

29 (9) ~~RESERVED~~

30 (10) ~~RESERVED~~

31 (11) ~~RESERVED~~

32 (12) ~~"Written Protocol" is a document prepared, signed, and dated by the Physician and Immunizing~~
33 ~~Pharmacist that shall contain the following:~~

34 (A) ~~the name of the Physician responsible for authorizing the Written Protocol;~~

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

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

1 (D) — ~~the screening questionnaires and safety procedures that shall at least include the then-~~
2 ~~current minimum standard screening questionnaire and safety procedures adopted by the~~
3 ~~Medical Board, the Board of Nursing, and the Board of Pharmacy pursuant to S.L. 2013-~~
4 ~~246, s. 6, and available at the North Carolina Medical Board's office and on its website~~
5 ~~(www.nemedboard.org).~~

6 (E) — ~~the procedures to follow, including any drugs required by the Immunizing Pharmacist for~~
7 ~~treatment of the patient, in the event of an emergency or adverse event following vaccine~~
8 ~~administration;~~

9 (F) — ~~the reporting requirements by the Immunizing Pharmacist to the Physician, including~~
10 ~~content and time frame; and~~

11 (G) — ~~the locations at which the Immunizing Pharmacist may administer immunizations or~~
12 ~~vaccinations.~~

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

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

18 (d) ~~With each dose of vaccine, either the Immunizing Pharmacist or a Pharmacy Intern shall give the most current~~
19 ~~vaccine information regarding the purpose, risks, benefits, and contraindications of the vaccine to the patient or legal~~
20 ~~representative. The Immunizing Pharmacist or Pharmacy Intern must ensure that the patient or legal representative~~
21 ~~has the opportunity to read, or to have read to him or her, the information provided and to have any questions answered~~
22 ~~prior to administration of the vaccine.~~

23 (e) ~~In agreeing to serve as a supervising Physician, the Physician shall agree to meet the following requirements:~~

24 (1) — ~~be responsible for the formulation or approval of the Written Protocol and review the Written~~
25 ~~Protocol and the services provided to patients under the Written Protocol, as set out in Subparagraph~~
26 ~~(b)(12) of this Rule;~~

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

29 (3) — ~~receive a periodic status reports from the Immunizing Pharmacist, including any problems or~~
30 ~~complications encountered.~~

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

32 (1) — ~~Drugs administered by an Immunizing Pharmacist under the provisions of this Rule shall be in the~~
33 ~~legal possession of:~~

34 (A) — ~~a pharmacy, which shall be the pharmacy responsible for drug accountability, including~~
35 ~~the maintenance of records of administration of the immunization or vaccination; or~~

36 (B) — ~~the Physician, who shall be responsible for drug accountability, including the maintenance~~
37 ~~of records of administration of the immunization or vaccination;~~

38 (2) — ~~Drugs shall be transported and stored at the proper temperatures indicated for each drug;~~

1 ~~(3) — Immunizing Pharmacists, while engaged in the administration of vaccines under the Written~~
2 ~~Protocol, shall have in their custody and control the vaccines identified in the Written Protocol and~~
3 ~~any other drugs listed in the Written Protocol to treat adverse events; and~~

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

6 ~~(g) Record Keeping and Reporting.~~

7 ~~(1) — An Immunizing Pharmacist shall maintain the following information, readily retrievable, in the~~
8 ~~pharmacy records in accordance with the applicable rules and statute regarding each administration:~~

9 ~~(A) — the name, address, and date of birth of the patient;~~

10 ~~(B) — the date of the administration;~~

11 ~~(C) — the administration site of injection (e.g., right arm, left leg, right upper arm);~~

12 ~~(D) — route of administration of the vaccine;~~

13 ~~(E) — the name, manufacturer, lot number, and expiration date of the vaccine;~~

14 ~~(F) — dose administered;~~

15 ~~(G) — the name and address of the patient's primary health care provider, as identified by the~~
16 ~~patient; and~~

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

18 ~~(2) — An Immunizing Pharmacist shall document the annual review with the Physician of the Written~~
19 ~~Protocol as required in this Rule.~~

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

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

26
27 *History Note: Authority G.S. 90-85.3(r); 90-85.15B;*
28 *Emergency Adoption Eff. September 10, 2004;*
29 *Temporary Adoption Eff. December 29, 2004;*
30 *Eff. November 1, 2005;*
31 *Amended Eff. February 1, 2008;*
32 *Emergency Amendment Eff. October 9, 2009;*
33 *Temporary Amendment Eff. December 29, 2009;*
34 *Temporary Amendment Expired on October 12, 2010;*
35 *Amended Eff. September 1, 2014; March 1, 2012;*
36 *Pursuant to G.S. 150B-21.3A rule is necessary without substantive public interest Eff. March 1,*
37 *2016.*

1 21 NCAC 32U .0102 is proposed for adoption as follows:

2

3 **21 NCAC 32U .0102 ADMINISTRATION OF LONG-ACTING INJECTABLES**

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

5

6 *History Note: Authority SL 2021-110;*

7 *Eff.*