TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY
VOLUME:
ISSUE:

1. Rule-Making Agency: North Carolina Board of Pharmacy

2. Rule citation & name: 21 NCAC 46 .2514 ADMINISTRATION OF LONG-ACTING INJECTABLES

3. Action: ☒ **Adoption** ☐ **Amendment** ☐ **Repeal**

4. Was this an Emergency Rule: ☐ **Yes** **Effective date:**
☒ **No**

5. Provide dates for the following actions as applicable:

a. Proposed Temporary Rule submitted to OAH: June 15, 2021

b. Proposed Temporary Rule published on the OAH website: June 22, 2021

c. Public Hearing date: August 2, 2021

d. Comment Period: June 15, 2021 to August 3, 2021

e. Notice pursuant to G.S. 150B-21.1(a3)(2): June 15, 2021

f. Adoption by agency on: August 5, 2021

g. Proposed effective date of temporary rule [if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3]: October 1, 2021

h. Rule approved by RRC as a permanent rule [See G.S. 150B-21.3(b2)]:

6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review.

☐ **A serious and unforeseen threat to the public health, safety or welfare.**
☒ **The effective date of a recent act of the General Assembly or of the U.S. Congress.**
Cite: Session Law 2021-3, Section 2.9
Effective date: October 1, 2021
☐ **A recent change in federal or state budgetary policy.**
Effective date of change:
☐ **A recent federal regulation.**
Cite:
Effective date:
☐ **A recent court order.**
Cite order:
☐ **State Medical Facilities Plan.**
☐ **Other:**

Explain: 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 becomes effective on October 1, 2021, and explicitly permits the Board of Pharmacy to adopt temporary rules to implement the section. The rule is being proposed as a temporary rule so that – by the effective date of the statute – the appropriate standards are 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 temporary 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.

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

See above. The statutory change becomes effective on October 1, 2021. Without a temporary rulemaking (which is expressly authorized by statute), the statute would become effective without any 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.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

☐ **Yes**
Agency submitted request for consultation on:
Consultation not required. Cite authority:

☒ **No**

9. Rule-making Coordinator: Clinton R. Pinyan

Phone: (336) 271-3157

E-Mail: cpinyan@brookspierce.com

Agency contact, if any: Jay Campbell

Phone: (919) 246-1055

E-Mail: jcampbell@ncbop.org

10. Signature of Agency Head*:

(see scanned signature on next page)

*** If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.**

Typed Name: William A. Mixon

Title: President

E-Mail: bmixon@ncbop.org

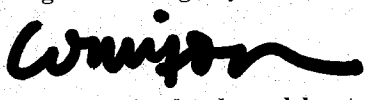
RULES REVIEW COMMISSION USE ONLY	
Action taken: ☐ Date returned to agency:	Submitted for RRC Review:

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

Yes

Agency submitted request for consultation on:
Consultation not required. Cite authority:

No

9. Rule-making Coordinator: Clinton R. Pinyan **Phone:** (336) 271-3157 **E-Mail:** cpinyan@brookspierce.com	**10. Signature of Agency Head*:**  *** If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.**
Agency contact, if any: Jay Campbell **Phone:** (919) 246-1055 **E-Mail:** jcampbell@ncbop.org	**Typed Name:** William A. Mixon **Title:** President **E-Mail:** bmixon@ncbop.org

Action taken:	Submitted for RRC Review:
Date returned to agency:	

4837-2101-8356.v1

21 NCAC 46 .2514 is adopted under temporary procedures with changes as follows:

21 NCAC 46 .2514 ADMINISTRATION OF LONG-ACTING INJECTABLES

(a) A [~~"long acting~~] "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; [~~an appropriately qualified practitioner;~~]

(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 90-85.15B.

(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 [~~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;*
Temporary Adoption Eff. October 1, 2021.