



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: <input checked="" type="checkbox"/> Adoption <input type="checkbox"/> Amendment <input type="checkbox"/> Repeal	
4. Was this an Emergency Rule: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Effective date:	
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: 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. <input type="checkbox"/> A serious and unforeseen threat to the public health, safety or welfare. <input checked="" type="checkbox"/> 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 <input type="checkbox"/> A recent change in federal or state budgetary policy. Effective date of change: <input type="checkbox"/> A recent federal regulation. Cite: Effective date: <input type="checkbox"/> A recent court order. Cite order: <input type="checkbox"/> State Medical Facilities Plan. <input type="checkbox"/> 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

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Agency contact, if any: Jay Campbell

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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:

Submitted for RRC Review:

☐ Date returned to agency:

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Typed Name: William A. Mixon

Title: President

E-Mail: bmixon@ncbop.org

Action taken:

Submitted for RRC Review:

Date returned to agency:

**GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2021**

**SESSION LAW 2021-3
HOUSE BILL 196**

AN ACT TO MAKE MODIFICATIONS TO COVID-19 RELIEF LEGISLATION AND
PROVIDE ADDITIONAL APPROPRIATIONS FOR THE EXPENDITURE OF FEDERAL
COVID-19 PANDEMIC RELIEF FUNDS.

The General Assembly of North Carolina enacts:

**PART I. APPROPRIATION OF FEDERAL CORONAVIRUS RESPONSE AND RELIEF
SUPPLEMENTAL APPROPRIATIONS ACT FUNDS**

APPROPRIATION OF COVID-19 FEDERAL FUNDS

SECTION 1.1.(a) Federal funds received by the State as authorized under the Consolidated Appropriations Act, 2021, (P.L. 116-260), are appropriated in the amounts provided in the notification of award from the federal government or any entity acting on behalf of the federal government to administer the federal funds. State agencies may, with approval of the Director of the Budget, spend these funds received from federal receipts and federal grants. The programs and grant amounts in the schedule set forth in this subsection are estimates of North Carolina's allocations to be deposited in the State's Treasury and administered by State agencies. This schedule is meant to be illustrative of federal grants that have been, or will be, received by the State from the Consolidated Appropriations Act, 2021, (P.L. 116-260).

<u>Program</u>	<u>Amount</u>
Governor's Emergency Education Relief Fund (GEER II)	\$42,920,546
Governor's Emergency Education Relief Fund – Emergency Assistance to Nonpublic Schools (EANS)	\$84,824,393
Higher Education Emergency Relief Fund (HEER II)	\$292,693,289
Farm Stress Program Block Grants	\$500,000
Fisheries Disaster Assistance	\$5,202,534
Emergency Food Assistance Program (TEFAP)	\$12,813,000
Older Americans Act – Congregate and Home-Delivered Meals	\$5,172,595
ELC Enhancing Detection through Coronavirus Response and Relief Supplemental Funds	\$603,677,156

SECTION 1.1.(b) The final amount of federal funds awarded for the following programs are not yet known, but are hereby appropriated in the same manner as provided in subsection (a) of this section: Specialty Crop Block Grants, Supplemental Nutrition Assistance Program (SNAP), Commodity Supplemental Food Program, and School Nutrition and Child and Adult Care Food Program.

**EMERGENCY NEEDS FOR ELEMENTARY AND SECONDARY SCHOOLS OF THE
STATE**

SECTION 1.2. S.L. 2021-1 is amended by adding a new section to read:

"SECTION 5A. The Department of Public Instruction shall use the funds reserved pursuant to subsection (c1) of Section 5 of this act as follows:



SECTION 2.8.(b) This section is effective when it becomes law.

PHARMACISTS/LONG-ACTING INJECTABLES

SECTION 2.9.(a) G.S. 90-85.15B is amended by adding a new subsection to read:

"(c1) An immunizing pharmacist may administer a long-acting injectable medication to persons at least 18 years of age pursuant to a specific prescription order initiated by a prescriber following a physical examination of the patient by the prescriber. An immunizing pharmacist who administers a long-acting injectable medication pursuant to this section shall do all of the following:

- (1) Maintain a record of any administration of a long-acting injectable performed by the immunizing pharmacist to the patient in a patient profile or record.
- (2) Within 72 hours after the administration of the long-acting injectable performed by the immunizing pharmacist to the patient, notify the prescriber regarding which medication and dosage was administered to the patient."

SECTION 2.9.(b) G.S. 90-85.3(i1) reads as rewritten:

"(i1) "Immunizing pharmacist" means a licensed pharmacist who meets all of the following qualifications:

- ...
- (6) Administers ~~vaccines~~ vaccines, long-acting injectable medications, or immunizations in accordance with G.S. 90-18.15B."

SECTION 2.9.(c) The North Carolina Board of Pharmacy may adopt temporary rules to implement this section.

SECTION 2.9.(d) This section becomes effective October 1, 2021.

NOTARY/VIDEO WITNESS EXTENSIONS

SECTION 2.10.(a) G.S. 10B-25(n) reads as rewritten:

"(n) This section shall expire at 12:01 A.M. on ~~March 1, 2021;~~ December 31, 2021; provided, however, all notarial acts made in accordance with this section and while this section is in effect shall remain effective and shall not need to be reaffirmed."

SECTION 2.10.(b) G.S. 10B-200(b) reads as rewritten:

"(b) This Article expires ~~March 1, 2021.~~ December 31, 2021."

SECTION 2.10.(c) This section becomes effective March 1, 2021.

VIRTUAL EDUCATION REQUIREMENTS/REAL ESTATE APPRAISERS

SECTION 2.11.(a) The North Carolina Appraisal Board may amend, extend, or adopt emergency rules to modify any educational requirements implemented by the Board, in accordance with Section 3.20 of S.L. 2020-97. Notwithstanding Section 3.20(e) of S.L. 2020-97, any emergency rules adopted pursuant to this section shall expire on December 31, 2021.

SECTION 2.11.(b) This section is effective when it becomes law.

HEALTH CARE PROVIDER LIABILITY CLARIFICATION

SECTION 2.13.(a) Section 3D.7(b) of S.L. 2020-3 reads as rewritten:

"SECTION 3D.7.(b) This section is effective when it becomes law and applies to acts or omissions occurring during either the time-pendency of Executive Order No. 116 issued on March 10, 2020, by Governor Roy A. Cooper, and or during any subsequent time period during which a state of emergency is declared to be in effect during calendar year 2020 by the Governor ~~Governor, in any year, in response to COVID-19."~~

SECTION 2.13.(b) The clarifications in this section are consistent with the intent and purpose of this section as originally enacted in S.L. 2020-3.

VACCINE VOLUNTEERS

SECTION 4.1. Except as otherwise provided, this act is effective when it becomes law.

In the General Assembly read three times and ratified this the 4th day of March, 2021.

s/ Philip E. Berger
President Pro Tempore of the Senate

s/ Tim Moore
Speaker of the House of Representatives

s/ Roy Cooper
Governor

Approved 4:07 p.m. this 11th day of March, 2021

21 NCAC 46 .2514 is adopted under temporary procedures 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 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 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.

1 (4) After administering long-acting injectables at a location other than a pharmacy, the Immunizing
2 Pharmacist shall return all unused prescription medications to the pharmacy or prescriber
3 responsible for the drugs.
4 (g) Record Keeping and Reporting.
5 (1) An Immunizing Pharmacist shall maintain the following information, readily retrievable, in the
6 pharmacy records in accordance with the applicable rules and statute regarding each
7 administration of a long-acting injectable:
8 (A) the name, address, and date of birth of the patient;
9 (B) the date of the administration;
10 (C) the administration site of injection (e.g., right arm, left leg, right upper arm);
11 (D) route of administration of the drug;
12 (E) the name, manufacturer, lot number, and expiration date of the drug;
13 (F) dose administered;
14 (G) the name and address of the prescriber; and
15 (H) the name or identifiable initials of the Immunizing Pharmacist.
16 (2) An Immunizing Pharmacist shall report to the prescriber adverse events associated with
17 administration of a long-acting injectable.
18 (h) The Immunizing Pharmacist shall maintain written policies and procedures for handling and disposal of used or
19 contaminated equipment and supplies.
20
21 History Note: Authority G.S. 90-85.3; 90-85.6; 90-85.15B;
22 Temporary Adoption Eff. October 1, 2021.