Notice is hereby given in accordance with G.S. 150B-21.2 that the Board of Pharmacy intends to adopt the rule cited as 21 NCAC 46 .2514.

Link to agency website pursuant to G.S. 150B-19.1(c): www.ncbop.org/rulemakings.htm

Proposed Effective Date: July 1, 2022

Public Hearing:
Date: April 28, 2022
Time: 10:00 a.m.
Location: The public hearing will be held remotely. The public can participate on Teams at https://tinyurl.com/2p8czkmb or may call 336-604-5350, conference ID 232 964 29#.

Reason for Proposed Action: 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 long-acting 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.

Comments may be submitted to: Jay Campbell, 6015 Farrington Rd Ste 201, Chapel Hill, NC 27517; email ncboprulemaking@ncbop.org

Comment period ends: May 2, 2022

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 after the adoption of the Rule. If the Rules Review Commission receives written and signed objections after the adoption of the Rule 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 facsimile transmission. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 984-236-1850.

Fiscal impact. Does any rule or combination of rules in this notice create an economic impact? Check all that apply.
☐ State funds affected
☐ Local funds affected
☐ Substantial economic impact (>= $1,000,000)
☐ Approved by OSBM
☒ No fiscal note required

SECTION .2500 - MISCELLANEOUS PROVISIONS

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.

Authority G.S. 90-85.3; 90-85.6; 90-85.15B.