

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;
- (2) a pharmacy intern who is under the direct, in-person supervision of an Immunizing Pharmacist; or
- (3) the patient at the direction and under the direct, in-person supervision 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.

*History Note: Authority G.S. 90-85.3; 90-85.6; 90-85.15B;
Temporary Adoption Eff. October 1, 2021;
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