

1 21 NCAC 46 .2514 is proposed as a temporary rule as follows:

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3 **21 NCAC 46 .2514 ADMINISTRATION OF LONG-ACTING INJECTABLES**

4 (a) A “long acting injectable” is drug product formulated to produce sustained release and gradual absorption of the  
5 active pharmaceutical ingredient over an extended period of time after administration by subcutaneous or  
6 intramuscular injection.

7 (b) "Administer" means the direct application of a drug to the body of a patient by injection by:

8 (1) an Immunizing Pharmacist or a pharmacy intern who is under the direct, in-person supervision of  
9 an Immunizing Pharmacist; or

10 (2) the patient at the direction of either an Immunizing Pharmacist or a health care provider authorized  
11 by North Carolina law to prescribe the long-acting injectable.

12 (c) In order to administer long-acting injectables, an Immunizing Pharmacist must:

13 (1) satisfy all requirements to be an “Immunizing Pharmacist” under G.S. 90-85.3(i1);

14 (2) document training on administering long-acting injectables both subcutaneously and  
15 intramuscularly. This training may include a program accredited by the American Council on  
16 Pharmaceutical Education (ACPE) or the North Carolina Association of Pharmacists, curriculum  
17 based programs from an ACPE-accredited school of pharmacy, state or local health department  
18 programs, or training by an appropriately qualified practitioner;

19 (3) notify the Board of the status as both an Immunizing Pharmacist and a pharmacist who  
20 administers long-acting injectables; and

21 (4) administer long-acting injectables in accordance with 90-85.15B.

22 (d) An Immunizing Pharmacist who, because of physical disability, is unable to obtain a current provider level CPR  
23 certification pursuant to G.S. 90-85.3(i1)(1), may administer long-acting injectables in the presence of a pharmacy  
24 technician or pharmacist who holds a current provider level CPR certification.

25 (e) Before each administration of a long-acting injectable, the Immunizing Pharmacist must personally and  
26 affirmatively conduct patient counseling that complies with Rule 2504 of this Chapter.

27 (f) The following requirements pertain to long-acting injectables administered by an Immunizing Pharmacist:

28 (1) Drugs administered by an Immunizing Pharmacist under the provisions of this Rule shall be in the  
29 legal possession of:

30 (A) a pharmacy, which shall be the pharmacy responsible for drug accountability, including  
31 the maintenance of records of administration of the long-acting injectable; or

32 (B) a prescriber, who shall be responsible for drug accountability, including the maintenance  
33 of records of administration of the long-acting injectable.

34 (2) Drugs shall be transported and stored at the proper temperatures indicated for each drug.

35 (3) Immunizing Pharmacists, while engaged in the administration of long-acting injectables, shall  
36 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.

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