

1 21 NCAC 46 .1820 is adopted **with changes** as published in 36:16 NCR 1390 as follows:

2

3 **21 NCAC 46 .1820**      **CODE OF ETHICS**

4 All pharmacists must comply with the American Pharmacist Association Code of Ethics, which is **hereby** incorporated  
5 **herein** by reference, along with all **subsequent** amendments or editions. ~~to that Code of Ethics.~~ **A copy of the Code**  
6 **of Ethics is available free of charge on the Board's website at <http://ncbop.org/lawandrules.htm>.** Any contrary conduct  
7 **is unprofessional conduct under G.S. 90-85.38.** ~~A copy of the Code of Ethics is available on the Board's website at~~  
8 ~~<http://ncbop.org/lawandrules.htm>.~~

9

10 *History Note:*    *Authority G.S. 90-85.3A; 90-85.6; 90-85.15A; 90-85.15B; ~~90-85.22;~~ 90-85.22; 90-85.26; 90-*  
11 *85.26A; 90-85.32; 90-85.33; 90-85.34; 90-85.38; ~~90-85.44;~~ 90-85.44; S.L. 2021-110, s. 4.(a);*  
12 *Eff. July 1, 2022.*

1 21 NCAC 46 .2507 is amended **with changes** as published in 36:16 NCR 1390 as follows:

2  
3 **21 NCAC 46 .2507 ADMINISTRATION OF VACCINES BY PHARMACISTS**

4 (a) An Immunizing Pharmacist shall administer only those vaccines or immunizations permitted by G.S. 90-85.15B  
5 and shall do so subject to all requirements of that statute and this Rule.

6 (b) The following words and terms, when used in this Rule, have the following meanings:

7 (1) "Administer" means the direct application of a drug to the body of a patient by injection, inhalation,  
8 ingestion, or other means by:

9 (A) an Immunizing **Pharmacist or Pharmacist;**

10 **(B)** a Pharmacy Intern or registered pharmacy technician who is under the ~~direct, in-person~~  
11 supervision of an Immunizing Pharmacist; or

12 ~~(B)(C)~~ the patient at the direction **and under the direct, in-person supervision** of either an  
13 Immunizing Pharmacist or a health care provider authorized by North Carolina law to  
14 prescribe the vaccine.

15 (2) "Immunizing Pharmacist" shall have the meaning provided in G.S. 90-85.3(i1).

16 (3) "Immunizing Pharmacy Personnel" means an Immunizing Pharmacist, or a Pharmacy Intern or a  
17 registered pharmacy technician who administers vaccines under the supervision of an Immunizing  
18 Pharmacist.

19 ~~(3)(4)~~ "Pharmacy Intern" shall have the meaning provided in 21 NCAC 46 .1317(29).

20 ~~(4)(5)~~ "Physician" means an M.D. or D.O. currently licensed with the North Carolina Medical Board who  
21 is responsible for the supervision of the Immunizing Pharmacist pursuant to the Written Protocol  
22 between the Immunizing Pharmacist and the Physician.

23 (6) RESERVED

24 (7) RESERVED

25 (8) RESERVED

26 (9) RESERVED

27 (10) RESERVED

28 (11) RESERVED

29 (12) "Written Protocol" is a document prepared, signed, and dated by the Physician and Immunizing  
30 Pharmacist that shall contain the following:

31 (A) the name of the Physician responsible for authorizing the Written Protocol;

32 (B) the name of the Immunizing Pharmacist authorized to administer vaccines;

33 (C) the immunizations or vaccinations that may be administered by the Immunizing  
34 Pharmacist;

35 (D) the screening questionnaires and safety procedures that shall at least include the then-  
36 current minimum standard screening questionnaire and safety procedures adopted by the  
37 Medical Board, the Board of Nursing, and the Board of Pharmacy pursuant to S.L. 2013-

1 246, s. 6, and available at the Board of Pharmacy's office and on its website  
2 (www.ncbop.org).

- 3 (E) the procedures to follow, including any drugs required by the Immunizing Pharmacist for  
4 treatment of the patient, in the event of an emergency or adverse event following vaccine  
5 administration;
- 6 (F) the reporting requirements by the Immunizing Pharmacist to the Physician, including  
7 content and time frame; and
- 8 (G) the locations at which the Immunizing Pharmacist may administer immunizations or  
9 vaccinations.

10 The Physician and the Immunizing Pharmacist shall review the Written Protocol at least annually and revise it if  
11 necessary.

12 (c) A registered pharmacy technician may administer those vaccines or immunizations permitted by G.S. 90-85.15B  
13 on behalf of an Immunizing Pharmacist, if the registered pharmacy technician does the following:

- 14 (1) Completes a practical training program that is approved by the Accreditation Council of Pharmacy  
15 Education;
- 16 (2) Holds a current basic CPR certification;
- 17 (3) Notifies the North Carolina Board of Pharmacy of immunizing pharmacy technician status;
- 18 (4) Is supervised by an Immunizing Pharmacist who is responsible for ensuring compliance with all  
19 legal requirements for vaccinations administered by a registered pharmacy technician under this  
20 Rule;
- 21 (5) Either (i) has an Immunizing Pharmacist on site and readily available to assist as needed, or (ii) has  
22 another licensed health care provider authorized to administer vaccines on site and readily available  
23 to assist as needed and has a supervising pharmacist readily available by phone or other  
24 telecommunications method for consultation as needed;
- 25 (6) Has the Immunizing Pharmacist or other health care provider who is present under Subparagraph  
26 (5) of this Paragraph review the patient's vaccine registry or other vaccination records and the  
27 screening questionnaire before the pharmacy technician administers the vaccine;
- 28 (7) Makes an offer of counseling to the [patient, which offer to counsel and any counseling should  
29 comply] in compliance with Rule .2504 of this Section; and
- 30 (8) Maintains documentation of three hours of immunization-related continuing education approved by  
31 the Accreditation Council for Pharmacy Education every two years. [years, designed to maintain  
32 competency in vaccine administration.]

33 ~~(e)(d)~~ An Immunizing Pharmacy Personnel Pharmacist who, because of physical disability, is are unable to obtain a  
34 current ~~provider-level~~ CPR certification pursuant to G.S. 90-85.3(i1)(1), may administer vaccines in the presence of a  
35 pharmacy technician, Pharmacy Intern, [Intern] technician or pharmacist who holds a current provider level CPR  
36 certification.

1 ~~(d)(e)~~ With each dose of vaccine, either the Immunizing Pharmacy Personnel Pharmacist or a Pharmacy Intern shall  
2 give the most current vaccine information regarding the purpose, risks, benefits, and contraindications of the vaccine  
3 to the patient or legal representative. The Immunizing Pharmacy Personnel Pharmacist or Pharmacy Intern must ensure  
4 that the patient or legal representative has the opportunity to read, or to have read to him or her, the information  
5 provided and to have any questions answered prior to administration of the vaccine.

6 ~~(e)(f)~~ In agreeing to serve as a supervising Physician, the Physician shall agree to meet the following requirements:

- 7 (1) be responsible for the formulation or approval of the Written Protocol and review the Written  
8 Protocol and the services provided to patients under the Written Protocol, as set out in Subparagraph  
9 (b)(12) of this Rule;
- 10 (2) be accessible to the Immunizing Pharmacist or be available through direct telecommunication for  
11 consultation, assistance, direction, and provide back-up coverage; and
- 12 (3) receive periodic status reports from the Immunizing Pharmacist, including any problems or  
13 complications encountered.

14 ~~(f)(g)~~ The following requirements pertain to drugs administered by an Immunizing Pharmacy Personnel Pharmacist:

- 15 (1) Drugs administered ~~by an Immunizing Pharmacist~~ under the provisions of this Rule shall be in the  
16 legal possession of:
  - 17 (A) a pharmacy, which shall be the pharmacy responsible for drug accountability, including  
18 the maintenance of records of administration of the immunization or vaccination; or
  - 19 (B) the Physician, who shall be responsible for drug accountability, including the maintenance  
20 of records of administration of the immunization or vaccination;
- 21 (2) Drugs shall be transported and stored at the proper temperatures indicated for each drug;
- 22 (3) Immunizing Pharmacy Personnel, Pharmacists, while engaged in the administration of vaccines  
23 under the Written Protocol, shall have in their custody and control the vaccines identified in the  
24 Written Protocol and any other drugs listed in the Written Protocol to treat adverse events; and
- 25 (4) After administering vaccines at a location other than a pharmacy, the Immunizing Pharmacy  
26 Personnel Pharmacist shall return all unused prescription medications to the pharmacy or Physician  
27 responsible for the drugs.

28 ~~(g)(h)~~ Record Keeping and Reporting.

- 29 (1) An Immunizing Pharmacist shall maintain the following information, readily retrievable, in the  
30 pharmacy records in accordance with the applicable rules and statute regarding each administration:
  - 31 (A) the name, address, and date of birth of the patient;
  - 32 (B) the date of the administration;
  - 33 (C) the administration site of injection (e.g., right arm, left leg, right upper arm);
  - 34 (D) route of administration of the vaccine;
  - 35 (E) the name, manufacturer, lot number, and expiration date of the vaccine;
  - 36 (F) dose administered;

1 (G) the name and address of the patient's primary health care provider, as identified by the  
2 patient; and

3 (H) the name or identifiable initials of the Immunizing Pharmacist.

4 (2) An Immunizing Pharmacist shall document the annual review with the Physician of the Written  
5 Protocol as required in this Rule.

6 (3) An Immunizing Pharmacist shall report adverse events associated with administration of a vaccine  
7 to either the prescriber, when administering a vaccine pursuant to G.S. 90-85.15B(a), or the patient's  
8 primary care provider, if the patient identifies one, when administering a vaccine pursuant to G.S.  
9 90-85.15B(b).

10 ~~(h)~~(i) The Immunizing Pharmacist shall maintain written policies and procedures for handling and disposal of used  
11 or contaminated equipment and supplies.

12 (j) The Immunizing Pharmacist shall comply with Rule .1820 of this Chapter in the practice of pharmacy pursuant to  
13 this Rule.

14  
15  
16

17 *History Note: Authority G.S. 90-85.3; 90-85.6; 90-85.15B; S.L. 2021-110, s. 4.(a) and (b);*  
18 *Eff. April 1, 2003;*  
19 *Emergency Amendment Eff. May 11, 2004;*  
20 *Temporary Amendment approved by RRC October 21, 2004;*  
21 *Amended Eff. February 1, 2008; November 1, 2005; November 1, 2004;*  
22 *Emergency Amendment Eff. October 9, 2009;*  
23 *Temporary Amendment Eff. December 29, 2009;*  
24 *Amended Eff. September 1, 2014; March 1, 2012;*  
25 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,*  
26 *2017;*  
27 *Amended Eff. June 1, ~~2020~~, 2020; July 1, 2022.*

1 21 NCAC 46 .2514 is adopted with changes as published in 36:16 NCR 1393 as follows:

2  
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~~ Pharmacist;

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

10 ~~(2)~~(3) the patient at the direction and under the direct, in-person supervision of either an Immunizing  
11 Pharmacist or a health care provider authorized by North Carolina law to prescribe the long-acting  
12 injectable.

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

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

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

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

23 (4) administer long-acting injectables in accordance with G.S. 90-85.15B, as well as all other pertinent  
24 State and federal laws and regulations (including but not limited to U.S. Food and Drug  
25 Administration Risk Evaluation and Mitigation Strategies).

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

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

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

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

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

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

- 1           (2)     Drugs shall be transported and stored at the proper temperatures indicated for each drug.
- 2           (3)     Immunizing Pharmacists, while engaged in the administration of long-acting injectables, shall have  
3                 in their custody and control drugs needed to treat adverse events.
- 4           (4)     After administering long-acting injectables at a location other than a pharmacy, the Immunizing  
5                 Pharmacist shall return all unused prescription medications to the pharmacy or prescriber  
6                 responsible for the drugs.

7 (g) Record Keeping and Reporting.

- 8           (1)     An Immunizing Pharmacist shall maintain the following information, readily retrievable, in the  
9                 pharmacy records in accordance with the applicable rules and statute regarding each administration  
10                of a long-acting injectable:

11           (A)     the name, address, and date of birth of the patient;

12           (B)     the date of the administration;

13           (C)     the administration site of injection (e.g., right arm, left leg, right upper arm);

14           (D)     route of administration of the drug;

15           (E)     the name, manufacturer, lot number, and expiration date of the drug;

16           (F)     dose administered;

17           (G)     the name and address of the prescriber; and

18           (H)     the name or identifiable initials of the Immunizing Pharmacist.

- 19           (2)     An Immunizing Pharmacist shall report to the prescriber adverse events associated with  
20                 administration of a long-acting injectable.

21 (h) The Immunizing Pharmacist shall maintain written policies and procedures for handling and disposal of used or  
22 contaminated equipment and supplies.

24 History Note: Authority G.S. 90-85.3; 90-85.6; 90-85.15B;

25 Eff. July 1, 2022.