

21 NCAC 46 .2403 is amended as published in 33:10 NCR 1079 as follows:

21 NCAC 46 .2403 DRUGS AND DEVICES TO BE DISPENSED

(a) Pursuant to the provisions of G.S. 90-85.34A(a)(3), prescription drugs and devices included in the following general categories may be dispensed by registered nurses in local health department clinics when prescribed for the indicated conditions:

- (1) Anti-tuberculosis drugs, as recommended by the North Carolina Department of Health and Human Services in the North Carolina Tuberculosis Policy Manual (available at www.ncdhhs.gov), when used for the treatment and control of tuberculosis;
- (2) Anti-infective agents used in the control of sexually-transmitted diseases as recommended by the United States Centers for Disease Control in the Sexually Transmitted Diseases Treatment Guidelines (available at www.cdc.gov);
- (3) Natural or synthetic hormones and contraceptive devices when used for the prevention of pregnancy;
- (4) Topical preparations for the treatment of lice, scabies, impetigo, diaper rash, vaginitis, and related skin conditions;
- (5) Vitamin and mineral supplements;
- (6) Opioid antagonists prescribed pursuant to G.S. 90-12.7; ~~and~~
- (7) Epinephrine auto-injectors prescribed pursuant to G.S. 115C-375.2A; ~~and 115C-375.2A.~~
- (8) Over-the-counter nicotine replacement therapies.

(b) Regardless of the provisions set out in this Rule, no drug defined as a controlled substance by the United States Controlled Substances Act, 21 U.S. Code 801 through 904, or regulations enacted pursuant to that Act, 21 CFR 1300 through 1308, or by the North Carolina Controlled Substances Act, G.S. 90-86 through 90-113.8, may be dispensed by registered nurses pursuant to G.S. 90-85.34A.

History Note: Authority G.S. 90-12.7; 90-85.6; 90-85.34A; 115C-375.2A;

Eff. March 1, 1987;

Amended Eff. September 1, 2016; January 1, 2015; August 1, 2014; May 1, 1989;

Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017; 2017.

Amended Eff. March 1, 2019.

21 NCAC 46 .2502 is amended **with changes** as published in 33:10 NCR 1079 as follows:

21 NCAC 46 .2502 RESPONSIBILITIES OF PHARMACIST-MANAGER

(a) The pharmacist-manager shall assure that prescription legend drugs and controlled substances are safe and secure within the pharmacy.

(b) The pharmacist-manager employed or otherwise engaged to supply pharmaceutical services may have a flexible schedule of attendance but shall be present for at least one-half the hours the pharmacy is open or 32 hours a week, whichever is less. A pharmacist employee not meeting this requirement may serve as **temporary** pharmacist-manager of the permit holder ~~temporarily~~ for a period not to exceed 90 days from the departure date of the previous pharmacist-manager, if the pharmacist employee is present at least 20 hours per week in the pharmacy.

(c) Whenever a change of ownership or change of pharmacist-manager occurs, the successor pharmacist-manager shall complete an inventory of all controlled substances in the pharmacy within 10 days. A written record of **such the** inventory, signed and dated by the successor pharmacist-manager, shall be maintained in the pharmacy with other controlled substances records for a period of three years.

(d) The pharmacist-manager shall develop and implement a system of inventory record-keeping and control **which** ~~that~~ will enable that pharmacist-manager to detect any shortage or discrepancy in the inventories of controlled substances at that pharmacy at the earliest practicable time.

(e) The pharmacist-manager shall maintain authority and control over any and all keys to the pharmacy and shall be responsible for the security of the pharmacy. ~~A pharmacy shall be secured to prohibit unauthorized entry if~~ **If** no pharmacist will be present in the pharmacy for a period of 90 minutes or **more, the pharmacy shall be secured to prohibit unauthorized entry, more.**

(f) These duties ~~are~~ **shall be** in addition to the specific duties of pharmacist-managers at institutional pharmacies and pharmacies in health departments as set forth in the **Rules rules** in this Chapter.

(g) A person shall not ~~simultaneously~~ serve as pharmacist-manager at more than one ~~pharmacy, unless: pharmacy at any one time except for~~

(1) ~~the person is serving simultaneously as pharmacist-manager at pharmacies holding a limited service permit; or pharmacies.~~

(2) ~~the person is serving simultaneously as pharmacist-manager at two pharmacies holding full service permits, one of which is a newly permitted pharmacy that has not yet begun providing pharmacy services to patients. When the newly permitted pharmacy begins providing pharmacy services to patients or six months from the issuance of the new pharmacy permit, whichever [comes] occurs sooner, the person [must] shall relinquish the [other] former pharmacist-manager position and notify the Board of having done so.~~

(h) When a pharmacy is to be closed permanently, the pharmacist-manager shall inform the Board and the United States Drug Enforcement Administration of the closing, arrange for the proper disposition of the **pharmaceuticals** ~~pharmaceuticals~~, and return the pharmacy permit to the Board's offices within 10 days of the closing date. If possible, notice of the closing shall be given to the public by posted notice at the pharmacy at least 30 days prior to the closing

1 date and 15 days after the closing date. Such notice shall notify the public that prescription files may be transferred to
2 a pharmacy of the patient's or customer's choice during the 30-day 30-day period prior to the closing date. During the
3 30-day 30-day period prior to the closing date, the pharmacist-manager, pharmacist-manager and the pharmacy's
4 owner (if the owner is other than the pharmacist-manager), shall transfer prescription files to another pharmacy chosen
5 by the patient or customer, upon request. Absent specific instructions from the patient or customer, the pharmacist-
6 manager, pharmacist-manager and the pharmacy's owner (if the owner is other than the pharmacist-manager), shall
7 transfer prescription files to another pharmacy for maintenance of patient therapy and shall inform the public of such
8 transfer by posted notice at the pharmacy for 15 days after the closing date, if possible. Controlled substance records
9 shall be retained for the period of time required by law.

10 (i) If possible, the pharmacist-manager shall ensure that notice of the temporary closing of any pharmacy for more
11 than 14 consecutive days is given to the public by posted notice at the pharmacy at least 30 days prior to the closing
12 date, and 15 days after the closing date. Such notice shall notify the public that prescription files may be transferred
13 to a pharmacy of the patient's or customer's choice during the 30-day 30-day period prior to the closing date. During
14 the 30-day 30-day period prior to the closing date, the pharmacist-manager, pharmacist-manager and the pharmacy's
15 owner (if the owner is other than the pharmacist-manager), shall transfer prescription files to another pharmacy chosen
16 by the patient or customer, upon request.

17 (j) The pharmacist-manager shall prepare a plan to safeguard prescription records and pharmaceuticals and minimize
18 the interruption of pharmacy services in the event of a natural disaster such as hurricane or flood.

19 (k) The pharmacist-manager shall separate from the dispensing stock all drug products more than six months out of
20 date.

21 (l) The pharmacist-manager shall report to the Board of Pharmacy information that reasonably suggests that there is
22 a probability that a prescription drug or device dispensed from a location holding a permit has caused or contributed
23 to the death of a patient or customer. This report shall be filed in writing on a form provided by the Board within 14
24 days of the owner representative or pharmacist-manager's becoming aware of the event. The pharmacist-manager shall
25 retain all documents, labels, vials, supplies, substances substances, and internal investigative reports relating to the
26 event. All such items shall be made available to the Board upon request.

27 (m) The Board shall not disclose the identity of a pharmacist-manager who makes a report under Paragraph (l) of this
28 Rule, except as required by law. No report made under Paragraph (l) of this Rule shall not be released except as
29 required by law.

30 (n) In any Board proceeding, the Board shall consider compliance with Paragraph (l) of this Rule as a mitigating
31 factor and noncompliance with Paragraph (l) of this Rule as an aggravating factor.

32 (o) The pharmacist-manager shall ensure that all starter doses of medication supplied to doctors' offices from the
33 pharmacy are accompanied by written materials advising the patient that such doses of medication may be supplied
34 by any pharmacy. Starter doses shall be limited to a 24 hour dose supply per patient.

35
36 *History Note:* Authority G.S. 90-85.6; 90-85.21; 90-85.25; 90-85.26; 90-85.32;
37 *Eff. May 1, 1989;*

1 *Amended Eff. April 1, 2006; February 1, 2005; August 1, 2002; December 1, 2001; April 1, 2001;*
2 *April 1, 1999; July 1, 1996; March 1, 1992; October 1, 1990;*
3 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,*
4 *2017-2017;*
5 *Amended Eff. March 1, 2019.*