

## REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina Board of Pharmacy

RULE CITATION: 21 NCAC 46 .2401

DEADLINE FOR RECEIPT: Thursday, July 10, 2014

**NOTE WELL:** *This request when viewed on computer extends several pages. Please be sure you have reached the end of the document.*

The Rules Review Commission staff has completed its review of this rule prior to the Commission's next meeting. The Commission has not yet reviewed this rule and therefore there has not been a determination as to whether the rule will be approved. You may call this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made:

*In (3), does your regulated public know what you mean by “a system of control and accountability?”*

*In (5), delete or define “suitable” before “safety-closure containers.”*

*In (6), what is considered a “suitable” record? Is there another rule that provides additional information as to what will be considered “suitable” for purposes of the maintenance of records?*

*Item (7) is a bit unclear given that most of the Items appear to be limitations set for the nurse? Is the intent that the pharmacist-manager is responsible for ensuring compliance with all Items?*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Of course, this will also require conforming changes to the attached copies of the rule. Please check to see that this paperwork is in order and is returned along with the revised rule.

Amber Cronk May  
Commission Counsel  
June 25, 2014

21 NCAC 46 .2401 is amended as published in 28:18 NCR 2213 as follows:

## **21 NCAC 46 .2401        MEDICATION IN HEALTH DEPARTMENTS**

A registered nurse employed by a local health department may dispense prescription drugs or devices under the following conditions:

- (1) Drugs or devices may be dispensed only to health department ~~patients;~~ patients, with the exception of opioid antagonists, which may be dispensed either to health department patients or to others as permitted by G.S. 90-106.2;
- (2) No drugs or devices may be dispensed except at health department clinics;
- (3) The health department shall secure the services of a pharmacist-manager who shall be responsible for developing and supervising a system of control and accountability of all drugs dispensed from the health department;
- (4) Only the general categories of drugs or devices listed in Rule .2403 may be dispensed by a health department registered nurse;
- (5) All drugs or devices dispensed pursuant to G.S. 90-85.34A and these rules shall be packaged in suitable safety-closure containers, where appropriate, and shall be properly labelled (including necessary auxiliary labels) so as to provide information necessary for use and all other information required by state and federal law;
- (6) A suitable and perpetual record of drugs or devices dispensed shall be maintained in the health department. The pharmacist-manager shall verify the accuracy of the records at least weekly, and where health department personnel dispense to 30 or more patients in a 24-hour period per dispensing site, the pharmacist-manager shall verify the accuracy of the records within 24 hours after dispensing occurs;
- (7) The duties of the pharmacist-manager set out in Paragraphs (1) through (6) in this Rule may be delegated to a pharmacist licensed by the Board. The pharmacist-manager shall remain personally responsible for compliance with all statutes, rules, and regulations governing the practice of pharmacy and dispensing of drugs.

*History Note:*    *Authority G.S. 90-85.6; 90-85.34A; 90-106.2;*  
*Eff. March 1, 1987;*  
*Amended Eff. August 1, 2014; May 1, 1989.*

JUNE 17, 2014

## REQUEST FOR TECHNICAL CHANGE

AGENCY: North Carolina Board of Pharmacy

RULE CITATION: 21 NCAC 46 .2403

DEADLINE FOR RECEIPT: Thursday, July 10, 2014

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The Rules Review Commission staff has completed its review of this rule prior to the Commission's next meeting. The Commission has not yet reviewed this rule and therefore there has not been a determination as to whether the rule will be approved. You may call this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made:

*Is the information referenced in (a)(1) and (a)(2) available online? If so, please include a website. If not, please indicate where a copy of this information can be obtained.*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amber Cronk May  
Commission Counsel  
June 25, 2014

# ORIGINAL

21 NCAC 46 .2403 is amended as published in 28:18 NCR 2213 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 defined by the latest edition of Drug Facts and Comparisons, as published by Facts and Comparison Div., J.B. Lippincott Co., or as recommended by the Tuberculosis Control Branch of the North Carolina Division of Health Services, 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;
- (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; and
- (5) Vitamin and mineral ~~supplements; and supplements.~~
- (6) Opioid antagonists prescribed pursuant to G.S. 90-106.2.

(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. 90-85.6; 90-85.34A; 90-106.2;  
Eff. March 1, 1987;  
Amended Eff. August 1, 2014; May 1, 1989.*

JUNE 17, 2014