

## REQUEST FOR TECHNICAL CHANGE

AGENCY: Board of Pharmacy

RULE CITATION: 21 NCAC 46 .2403

**DEADLINE FOR RECEIPT: Thursday, February 7, 2019**

**PLEASE NOTE:** *This request may extend to 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 our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

*In the Introductory Statement, the Register was 33:10. Please correct this.*

*In (a)(8), I am simply asking – this over-the-counter therapy requires a prescription?*

*In the History Note, you will reflect the amendment like this:*

*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;  
Amended Eff. March 1, 2019.*

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

Amanda J. Reeder  
Commission Counsel  
Date submitted to agency: January 24, 2019

21 NCAC 46 .2403 is amended as published in 33:14 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](http://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](http://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. March 1, 2019; 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.*

## REQUEST FOR TECHNICAL CHANGE

AGENCY: Board of Pharmacy

RULE CITATION: 21 NCAC 46 .2502

### **DEADLINE FOR RECEIPT: Thursday, February 7, 2019**

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 our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

*In the Introductory Statement, the Register was 33:10. Please correct this.*

*In (a), line 4, what is "safe and secure"? Does your regulated public know?*

*In (b), lines 6-7, do you need to retain "may have a flexible schedule of attendance but", given the remaining language in the sentence?*

*On line 9, do you need "temporarily" given that it is followed by "for a period not to exceed 90 days"?*

*In (c), line 12, replace "such" with "the"*

*In (d), line 15, replace "which" with "that"*

*On line 17, what is a "practicable time"? Who determines what is "practicable"?*

*In (e), line 19, unauthorized entry by whom? I would imagine it is those not employed by the pharmacy, but this prohibition is only against unauthorized entry when the pharmacist is not present. Does this mean unauthorized entry is authorized when the pharmacist is present? Also, entry to where?*

*In (f), line 21, consider replacing "are" with "shall be"*

*On line 22, make "rules" lowercase.*

*In (g), on line 23, you state "simultaneously" and then you restate this on lines 25 and 27. I don't think you need it all three places.*

*In (g)(2), lines 28 and 29, what is "newly" permitted? Who determines this?*

*On line 30, consider replacing "comes" with "occurs"*

*On line 31, consider replacing "must" with "shall"*

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*On line 31, what is the “other” position they are relinquishing? Is the idea that they will stop serving the “newly permitted” pharmacy and go back to their old position?*

*In (h), line 34, what is “proper”? Does your regulated public know?*

*On line 34, insert a comma after “pharmaceuticals”*

*On line 35, who will determine if this is “possible”? Based upon what?*

*In (h), Page 2, line 1, I believe that “30-day” should be hyphenated both places.*

*On line 2, delete the comma after “pharmacist-manager”*

*Also on line 2, should the “and” before “pharmacy’s owner” be “or”?*

*On line 4, delete the comma after “pharmacist-manager”*

*Also on line 4, should the “and” before “pharmacy’s owner” be “or”?*

*On lines 6-7, who decides what is “possible”?*

*In (i), line 8, who decides if this is “possible”?*

*On line 8, so that I’m clear – the temporary closing is 15 consecutive days or more, but not permanent?*

*On line 11, I believe “30-day” should be hyphenated in both places.*

*On line 12, delete the comma after “pharmacist-manager”*

*In (j), is this the reason you are citing to G.S. 90-85.25 in the History Note? If not, why is this statute cited to in the History Note?*

*On line 15, what do you mean by “minimize”?*

*In (l), line 19, I suggest simply stating “Board” to be consistent with the other references in the Rule [see (g)(2) and (h)]*

*On line 19, what do you mean by “reasonably” Reasonable to whom?*

*On line 20, what is a “probability”?*

*On line 21, what are the contents of this form and where can it be obtained?*

*On line 22, what is an “owner representative”? Is this the same as the “designated agent” in G.S. 90-85.26(b)?*

*On line 23, insert a comma after “substances”*

*What is the purpose of Paragraph (m)?*

Amanda J. Reeder  
Commission Counsel  
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*In the History Note, you will reflect the amendment like this:*

*History Note: Authority G.S. 90-85.6; 90-85.21; 90-85.25; 90-85.26; 90-85.32;  
Eff. May 1, 1989;  
Amended Eff. April 1, 2006; February 1, 2005; August 1, 2002; December 1, 2001; April 1, 2001;  
April 1, 1999; July 1, 1996; March 1, 1992; October 1, 1990;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,  
2017;  
Amended Eff. March 1, 2019.*

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

Amanda J. Reeder  
Commission Counsel  
Date submitted to agency: January 24, 2019

21 NCAC 46 .2502 is amended as published in 33:14 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 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 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 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 no pharmacist will be present in the pharmacy for a period of 90 minutes or more.

(f) These duties are in addition to the specific duties of pharmacist-managers at institutional pharmacies and pharmacies in health departments as set forth in the 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 sooner, the person must relinquish the other 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 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 date and 15 days after the closing date. Such notice shall notify the public that prescription files may be transferred to a pharmacy of the

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

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

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

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

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

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

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

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

33  
34 *History Note:* Authority G.S. 90-85.6; 90-85.21; 90-85.25; 90-85.26; 90-85.32;

35 *Eff. May 1, 1989;*

36 *Amended Eff. March 1, 2019; April 1, 2006; February 1, 2005; August 1, 2002; December 1, 2001;*

37 *April 1, 2001; April 1, 1999; July 1, 1996; March 1, 1992; October 1, 1990;*

1                   *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,*  
2                   *2017.*