REQUEST FOR TECHNICAL CHANGE

AGENCY: Board of Pharmacy

RULE CITATION: 21 NCAC 46 .1412

DEADLINE FOR RECEIPT: Wednesday, December 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. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Line 5, define or delete "well lighted"

Line 5, if "well lighted" remains in the rule, add a comma prior to the "and"

Lines 5 and 14, define or delete "sufficient"

Lines 8, 9, 12, 13, and 14, consider beginning these items in the list with a lowercase letter

Line 20, delete "at a minimum,"

Line 21, delete "such"

Line 21, replace the period after "apply" with a semicolon and add an "and"

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

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, November 26, 2014

21 NCAC 46 .1412 is amended as published in 29:02 NCR166 as follows:

21 NCAC 46 .1412 PHYSICAL REQUIREMENTS

A health care facility pharmacy shall have sufficient floor space allocated to it to ensure that drugs are prepared in sanitary, well lighted and enclosed places. It shall have sufficient equipment and physical facilities for proper compounding, dispensing, and storage of drugs, including parenteral preparations. In addition to the requirements of Section .1600 of this Chapter, the equipment and physical facilities shall include the following:

(1) ~~Compounding and dispensing areas;~~ Dispensing areas;

(2) ~~Physically separate parenteral solution additive area when parenteral solutions are compounded as described in~~ Compounding areas that comply with Section .2800 ~~– Sterile Parenteral Pharmaceuticals~~ of this Chapter;

(3) Receiving and storage areas;

(4) Packaging and repackaging areas;

(5) Office space sufficient to allow for administrative functions without interference with the safe compounding and dispensing of medications and security of the pharmacy;

(6) Storage. All drugs shall be stored in designated areas within the pharmacy or decentralized pharmacy sufficient to provide sanitation to prevent contamination, moisture control, and security to prevent access from unauthorized personnel. Controlled substances shall be stored in compliance with applicable Federal and State laws and regulations. Alcohol and flammables shall be stored in areas that shall, at a minimum, meet basic local building code requirements for the storage of volatile substances and such other laws, ordinances, or regulations that may apply.

(7) Security. All areas occupied by the health care facility pharmacy, to include auxiliary drug supplies and unit dose carts, shall remain secured at all times.

History Note: *Authority G.S. 90-85.6; 90-85.21; 90-85.32;*
Eff. May 1, 1997;
Amended Eff. January 1, 2015; March 1, 2013.

26 NCAC 46 .1810 is repealed as published in 29:02 NCR 166 as follows:

21 NCAC 46 .1810 COMPOUNDING

History Note: *Authority G.S. 90-85.6; 90-85.32;*
Eff. September 1, 1995;
Amended Eff. August 1, 1998; ~~1998.~~
Repealed Eff. January 1, 2015.

REQUEST FOR TECHNICAL CHANGE

AGENCY: Board of Pharmacy

RULE CITATION: 21 NCAC 46 .2401

DEADLINE FOR RECEIPT: Wednesday, December 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. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Line 8, replace the comma after "90-106.2" with a semicolon

Line 14, add "of this Section" after ".2403"

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

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, November 26, 2014

21 NCAC 46 .2401 is amended as published in 29:06 NCR 661 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, with the exception ~~of~~ of: (a) opioid antagonists, which may be dispensed either to health department patients or to others as permitted by G.S. ~~90-106.2;~~ 90-106.2, and (b) epinephrine auto-injectors, which may be dispensed either to health department patients or to school personnel as permitted by G.S. 115C-375.2A.

(2) No drugs or devices may by dispensed except at health department clinics;

(3) The health department shall secure the services of a pharmacist-manager who shall be responsible for compliance with all statutes, rules, and regulations governing the practice of pharmacy and dispensing of drugs at 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, labeled, and otherwise dispensed in compliance with state and federal law, and records of dispensing shall be kept in compliance with state and federal law. 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.

History Note: *Authority G.S. 90-85.6; 90-85.34A; 90-106.2; 115C-375.2A;*
Eff. March 1, 1987;
Amended Eff. January 1, 2015; August 1, 2014; May 1, 1989.

21 NCAC 46 .2403 is amended as published in 29:06 NCR 661 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; ~~and~~

(6) Opioid antagonists prescribed pursuant to G.S. ~~90-106.2.~~ 90-106.2; and

(7) Epinephrine auto-injectors prescribed pursuant to G.S. 115C-375.2A.

(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; 115C-375.2A;*
Eff. March 1, 1987;
Amended Eff. January 1, 2015; August 1, 2014; May 1, 1989.

REQUEST FOR TECHNICAL CHANGE

AGENCY: Board of Pharmacy

RULE CITATION: 21 NCAC 46 .2801

DEADLINE FOR RECEIPT: Wednesday, December 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. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Line 8, replace "may" with "shall"

Lines 9 and 10, consider beginning these items in the list with a lowercase letter

Line 11, consider the following rewrite:

> *"...drug preparation. The pharmacy shall not dispense..."*

Line 14 thru 16, this is a cumbersome sentence. What is the pharmacy "supplying" to the practitioner"? What is meant by "with compounding drug products to administer to patients"? What is meant by "compounding for office use"? Isn't the issue of "within the scope of their professional practice" and "shall comply with applicable federal law" outside the purview of the Pharmacy Practice Act? Consider the following rewrite:

> *"A physician or practitioner authorized to prescribe compound drugs may receive supplies from pharmacies."*

Paragraphs (d) and (e), review the incorporation standards set forth in G.S. 150B-21.6. Please specify, here or in Paragraph (k) if subsequent amendments and editions will be included.

Lines 18, 19, 23, and 24, is the use of the < > correct for this citation? Please clarify.

Line 27, define or delete "ready"

Lines 30 through 31, consider the following rewrite:

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Commission Counsel
Date submitted to agency: Wednesday, November 26, 2014

"The pharmacist-manager, or the pharmacist-manager's designated pharmacist, of a..."

Line 31, delete the clause between the dash marks

Line 33, delete "so"

Line 34, delete "(if applicable)"

Line 36, and page 2, line 1, replace "retains responsibility" with "shall be responsible"

Page 2, line 5, define or delete "immediately"

Page 2, line 20, replace "which" with "that"

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

Abigail M. Hammond
Commission Counsel
Date submitted to agency: Wednesday, November 26, 2014

21 NCAC 46 .2801 is amended with changes as published in 29:02 NCR 166:

SECTION .2800 – ~~STERILE PHARMACEUTICALS~~ COMPOUNDING

21 NCAC 46 .2801 ~~SCOPE AND PURPOSE~~ COMPOUNDING

(a) A pharmacy may dispense a compounded drug preparation to a patient only pursuant to a prescription that is valid and complies with all requirements of the law, including 21 NCAC 46 .1801. In advance of dispensing the compounded drug preparation, a pharmacy may prepare the drug preparation only:

(1) Upon the pharmacy's receipt of a valid prescription order for an individual patient; or

(2) In anticipation of a prescription order based on an established history of receiving prescription orders for the compounded drug preparation, but the pharmacy may not dispense the compounded drug preparation until the pharmacy receives a valid prescription order for an individual patient.

(b) Compounded drug preparations shall not be offered to other entities for resale.

(c) A pharmacy may supply practitioners authorized by law to prescribe drugs with compounded drug products to administer to patients within the scope of their professional practice. Such compounding for office use shall comply with applicable federal law.

(d) The preparation, labeling, and dispensing of non-sterile compounded drug preparations shall comply with standards established by United States Pharmacopeia chapter <795>, including all United States Pharmacopeia chapters and standards incorporated into chapter <795> by reference, governing both the non-sterile compounded drug preparations and the physical and environmental conditions under which non-sterile compounded drug preparations are prepared, labeled, and dispensed.

(e) The preparation, labeling, and dispensing of sterile compounded preparations shall comply with standards established by United States Pharmacopeia chapter <797>, including all United States Pharmacopeia chapters and standards incorporated into chapter <797> by reference, governing both the sterile compounded products and the physical and environmental conditions under which sterile compounded products are prepared, labeled, and dispensed.

(f) A pharmacy that prepares, labels, or dispenses sterile compounded preparations shall have ready access to current United States Pharmacopeia standards and references on the compatibility, stability, storage, handling and preparation of compounded drugs.

(g) The pharmacist-manager of a pharmacy where compounded drug preparations are prepared, labeled, or dispensed – or the pharmacist-manager's designated pharmacist – shall be knowledgeable in the specialized functions of preparing, labeling, and dispensing compounded drug preparations. If the pharmacist-manager chooses to designate another pharmacist for this purpose, the pharmacist-manager shall so notify the Board on the pharmacy's permit application (if applicable) and, in writing, within 15 days of any change in the designation. Notwithstanding the pharmacist-manager's designation of another pharmacist as knowledgeable in the specialized functions of preparing, labeling, and dispensing compounded drug preparations, the pharmacist-manager retains

responsibility for ensuring the pharmacy's compliance with all statutes, rules, and standards that govern such activities.

(h) In addition to complying with all recordkeeping and labeling requirements specified or referred to by United States Pharmacopeia chapters <795> or <797>, a pharmacy that prepares, labels, or dispenses compounded drug preparations shall create and maintain a record-keeping system that enables the pharmacy immediately to identify every compounded drug preparation prepared, labeled, or dispensed in the past three years. This recordkeeping system may be created and maintained electronically in compliance with 21 NCAC 46 .2508.

~~[(i) The labeling of all compounded drug preparations shall bear a lot number sufficient to identify the preparation, the date the preparation was prepared, and the identity of the pharmacist responsible for compounding the preparation. The pharmacy shall maintain records of all lot numbers assigned to compounded drug preparations. These records may be created and maintained electronically in compliance with 21 NCAC 46 .2508.]~~

~~[(j)]~~ (i) The pharmacist-manager of a pharmacy that prepares, labels, or dispenses compounded drug preparations shall comply with all quality assurance requirements and standards of United States Pharmacopeia chapters <795> and <797>.

~~[(k)]~~ (j) In addition to the requirements of this Section, the compounding of radiopharmaceutical drug products shall comply with Section .2700 of this Chapter.

(k) United States Pharmacopeia chapters <795> or <797> may be inspected at the offices of the Board during its normal hours of operation. Copies also may be obtained from the U.S. Pharmacopeial Convention (www.usp.org), as part of the "USP on Compounding: A Guide for the Compounding Practitioner," as an electronic publication, which cost one hundred dollars ($100.00) as of the effective date of the last amendment to this Rule.

~~The purpose of this Section is to provide standards for the preparation, labeling, and distribution of sterile products by licensed pharmacists, pursuant to an order or prescription. These standards are intended to apply to all sterile products, notwithstanding the location of the patient (e.g., home, hospital, nursing home, hospice, doctor's office).~~

History Note: *Authority G.S. 90-85.6; 90-85.32;*
Eff. October 1, 1990;
Amended Eff. January 1, 2015; April 1, 2003.

26 NCAC 46 .2802 - .2808 are repealed as published in 29:02 NCR 166 as follows:

21 NCAC 46 .2802	**DEFINITIONS**
21 NCAC 46 .2803	**REQ/PHARMACIES DISPENSING STERILE PHARMACEUTICALS**
21 NCAC 46 .2804	**RESPONSIBILITIES OF PHARMACIST-MANAGER**
21 NCAC 46 .2805	**LABELING**
21 NCAC 46 .2806	**RECORDS AND REPORTS**
21 NCAC 46 .2807	**ANTI-NEOPLASTIC AGENTS**
21 NCAC 46 .2808	**QUALITY ASSURANCE**

History Note: *Authority G.S. 90-85.6.*
Eff. October 1, 1990;
Amended Eff. March 1, 2013; February 1, 2006; April 1, 2003; September 1, 1995;
Repealed Eff. January 1, 2015.