21 NCAC 46 .1412 is amended with changes 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~~ 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 ~~shall, at a minimum,~~ meet basic local building code requirements for the storage of volatile substances and ~~such~~ all other laws, ordinances, or regulations that may ~~apply.~~ apply; and

(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.

21 NCAC 46 .2401 is amended with changes 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,~~] 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.~~] 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 of this Section 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 .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]~~ shall prepare the compounded drug preparation only:

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

(2) ~~[In]~~ in anticipation of a prescription order based on an established history of receiving prescription orders for the compounded drug preparation. ~~[preparation, but the pharmacy may not dispense the]~~ Any compounded drug preparation prepared in anticipation of a prescription order shall not be dispensed 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 compounded drug products to practitioners authorized by law to prescribe drugs ~~[with compounded drug products]~~ for those practitioners to administer to those practitioners' patients. ~~[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 the standards established by United States Pharmacopeia chapter <795>, including all United States Pharmacopeia chapters and standards incorporated into chapter <795> by ~~[reference,]~~ reference and including all subsequent amendments and editions of the same, 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,]~~ reference and including all subsequent amendments and editions of the same, 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~~] maintain a reference library in the pharmacy including the current United States Pharmacopeia standards and references on the compatibility, stability, storage, [~~handling~~] handling, and preparation of compounded drugs. These references may be either hard copy or electronically accessible.

(g) ~~[The pharmacist-manager of]~~ In a pharmacy where compounded drug preparations are prepared, labeled, or ~~[dispensed –]~~ dispensed, the pharmacist-manager 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]~~ shall be responsible 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 upon request 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, that 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.