21 NCAC 46 .2801 is proposed for amendment with changes as follows:

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) 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) In addition to the requirements of this Section, the compounding of radiopharmaceutical drug products shall comply with Section .2700 of this Chapter.

(l) United States Pharmacopeia chapters <795> or <797> may be inspected at the offices of the Board during its normal hours of operation. Copes 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. November 1, 2014; April 1, 2003.