SECTION .2800 – COMPOUNDING

21 NCAC 46 .2801 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 shall prepare the compounded 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. 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 for those practitioners to administer to those practitioners' patients. 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 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 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 maintain a reference library in the pharmacy including the current United States Pharmacopeia standards and references on the compatibility, stability, storage, handling, and preparation of compounded drugs. These references may be either hard copy or electronically accessible.

(g) In a pharmacy where compounded drug preparations are prepared, labeled, or 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 notify the Board on the pharmacy's permit application 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 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 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>.

(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.

History Note: *Authority G.S. 90-85.6; 90-85.32;*
Eff. October 1, 1990;

Amended Eff. January 1, 2015; April 1, 2003.

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.