

REQUEST FOR TECHNICAL CHANGE

AGENCY: Board of Pharmacy

RULE CITATION: 21 NCAC 46 .2801

DEADLINE FOR RECEIPT: Friday, July 9, 2021

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 (g), line 35, I suggest removing the comma after "and" and "writing"

In (j), Page 2, line 13, consider replacing "must" with "shall"

In (l), line 19, what are "normal" operating hours? Does your regulated public know the hours?

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

21 NCAC 46 .2801 is amended **with changes** as published in 35:20 NCR 2249 as follows:

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,

1 and dispensing compounded drug preparations, the pharmacist-manager shall be responsible for ensuring the
2 pharmacy's compliance with all statutes, rules, and standards that govern such activities.

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

8 (i) The pharmacist-manager of a pharmacy that prepares, labels, or dispenses compounded drug preparations shall
9 comply with all quality assurance requirements and standards of United States Pharmacopeia chapters <795> and
10 <797>.

11 ~~(j) Between January 1 and March 31 of each year, any pharmacy permitted by the Board that has prepared, labeled,~~
12 ~~or dispensed any compounded drug (for any patient or other person, either within or outside North Carolina) during~~
13 ~~the immediately preceding calendar year must update all information regarding its services in the National~~
14 ~~Association of Boards of Pharmacy's e-Profile Connect system at <https://dashboard.nabp.pharmacy>.~~
15 ~~<https://dashboard.nabp.pharmacy>.~~

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

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

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23 *History Note: Authority G.S. 90-85.6; 90-85.21A; 90-85.26; 90-85.32.*

24 *Eff. October 1, 1990;*

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

26 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,*
27 *2017; 2017.*

28 *Amended Eff. August 1, 2021.*