NOTICE OF TEXT
[Authority G.S. 150B-21.2(c)]

OAH USE ONLY
VOLUME:
ISSUE:

CHECK APPROPRIATE BOX:

- [X] **Notice with a scheduled hearing**
- [ ] **Notice without a scheduled hearing**
- [ ] **Republication of text. Complete the following cite for the volume and issue of previous publication, as well as blocks 1 - 4 and 7 - 14. If a hearing is scheduled, complete block 5.**
  Previous publication of text was published in Volume: Issue:

1. Rule-Making Agency: Board of Pharmacy

2. Link to agency website pursuant to G.S. 150B-19.1(c): www.ncbop.org/rulemakings.htm

3. Proposed Action -- Check the appropriate box(es) and list rule citation(s) beside proposed action:

- [ ] **ADOPTION:**
- [X] **AMENDMENT:** 21 NCAC 46 .2801
- [ ] **REPEAL:**
- [ ] **READOPTION with substantive changes:**
- [ ] **READOPTION without substantive changes:**
- [ ] **REPEAL through READOPTION:**

4. Proposed effective date: 08/01/2021

5. Is a public hearing planned? Yes

If yes:

Date	Time	Location
06/15/2021	10:00 a.m.	The public hearing will be held remotely. The public can participate on Teams at https://tinyurl.com/yfvbubpp or may call 336-604-5350, conference ID 946 782 795#.

6. If no public hearing is scheduled, provide instructions on how to demand a public hearing:

7. Explain Reason For Proposed Rule(s):
Section 503A of the Federal Food, Drug and Cosmetic Act strictly limits the compounding of human drug products in states that have not entered into a memorandum of understanding with the Secretary of Health and Human Services with respect to gathering and providing certain information to the FDA. 21 U.S.C. § 353a(b)(3)(B). The consequence of not entering the memorandum of understanding would be to prevent North Carolina compounding pharmacies from shipping compounded human drug products outside of the State if those exceed 5 percent of the total prescriptions dispensed by the pharmacy. This alternative would cause a number of North Carolina pharmacies to sharply curtail shipping compounded prescriptions to their patients in other states, causing financial harm, disadvantaging those pharmacies with respect to businesses located in other states that do enter the memorandum of understanding, and disrupting patient service. Moreover, the requirement to constantly remain under the alternative 5 percent cap, upon threat of prosecution, would cause undue risks and perpetual tracking costs to many pharmacies. The threats and costs imposed by the alternative has the effect (if not the intention) of compelling states to enter into the memorandum of understanding. Pharmacies are already required by law to provide all the subject information upon request by the North Carolina Board of Pharmacy. The memorandum provides that, rather than being collected by each state, the data will be collected by the National Association of Boards of Pharmacy through its e-profile system in which all North Carolina-permitted pharmacies already participate, in order to promote efficiencies for both the pharmacies and the Board. This rule implements the memorandum of understanding and Section 503A of the Federal Food, Drug and Cosmetic Act. In addition, it updates certain information about costs and sources for the public to acquire compounding standards.

8. Procedure for Subjecting a Proposed Rule to Legislative Review: If an objection is not resolved prior to the adoption of the rule, a person may also submit written objections to the Rules Review Commission. If the Rules Review Commission receives written and signed objections in accordance with G.S. 150B-21.3(b2) from 10 or more persons clearly requesting review by the legislature and the Rules Review Commission approves the rule, the rule will become effective as provided in G.S. 150B-21.3(b1). The Commission will receive written objections until 5:00 p.m. on the day following the day the Commission approves the rule. The Commission will receive those objections by mail, delivery service, hand delivery, or email. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 984-236-1850.

Rule(s) is automatically subject to legislative review. Cite statutory reference:

9. The person to whom written comments may be submitted on the proposed rule(s):

Name:	Jay Campbell
Address:	6015 Farrington Road, Suite 201
	Chapel Hill, NC 27517
Phone (optional):	
Fax (optional):	919-246-1056
EMail (optional)	ncboprulemaking@ncbop.org

10. Comment Period Ends: 06/15/2021 at 10:00 a.m.

11. Fiscal impact. Does any rule or combination of rules in this notice create an economic impact? Check all that apply.

No fiscal note required

12. Rule-making Coordinator:

Name: Clinton R. Pinyan
336-271-3157
cpinyan@brookspierce.com

Agency contact, if any:

Name: Jay Campbell
Phone: 919-246-1050
Email: ncboprulemaking@ncbop.org

13. The Agency formally proposed the text of this rule(s) on

Date: 03/23/2021

21 NCAC 46 .2801 is proposed for amendment 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,

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

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

~~(k)~~ (l) 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 a free download ~~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.

Authority G.S. 90-85.6; 90-85.21A; 90-85.26; 90-85.32.