



NOTICE OF TEXT

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

OAH USE ONLY

VOLUME: 38

ISSUE: 24

CHECK APPROPRIATE BOX:

- 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:

AMENDMENT: [21 NCAC 46 .1401](#)

REPEAL:

READOPTION with substantive changes:

READOPTION without substantive changes:

REPEAL through READOPTION:

4. Proposed effective date: [11/01/2024](#)

5. Is a public hearing planned? [Yes](#)

If yes:

Date	Time	Location
07/09/2024	9:30 a.m.	North Carolina Board of Pharmacy, 6015 Farrington Road, Suite 201, Chapel Hill, North Carolina 27517.

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

7. Explain Reason For Proposed Rule(s):

The Board proposes to amend its Rule .1401, which deals with the process of health care facilities registering with, and being issued permits by, the Board. The existing rule requires separate permits when drugs are dispensed from "separate locations" owned by a health care facility. This has caused confusion for entities -- such as larger hospitals -- that have multiple dispensing areas in the same hospital building or in attached or contiguous campus buildings. The proposed amendment would make clear that separate dispensing areas for inpatient populations may operate under one permit, so long as they are in the same building or in a building on property contiguous to the principal permitted location. The amendment would further remove unnecessary provisions covered by other statutes or rules. The rule amendment was recommended by a committee made up of Board members, pharmacists from hospitals of differing sizes, and pharmacists from other health care facility settings (such as long term care).

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 Rd Ste 201
Chapel Hill, NC 27517
Phone (optional):
Fax (optional):
EMail (optional) ncboprulemaking@ncbop.org

10. Comment Period Ends: 08/16/2024

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:
Email: ncboprulemaking@ncbop.org

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

Date: 05/21/2024

1 21 NCAC 46 .1401 is proposed for amendment as follows:

2
3 **SECTION .1400 - HOSPITALS: OTHER HEALTH FACILITIES**

4
5 **21 NCAC 46 .1401 REGISTRATION AND PERMITS**

6 ~~(a) Registration Required.~~ All Health Care Facilities ~~places providing services which embrace within the practice of~~
7 ~~pharmacy shall apply for and receive a pharmacy permit. register with the North Carolina Board of Pharmacy as~~
8 ~~provided in G.S. 90-85.21. G.S. 90-85.21 and acquire a permit to do so. Application for such registration and permit~~
9 ~~shall be on forms provided by the Board. If the Board is satisfied that proper facilities and adequately trained and~~
10 ~~properly licensed personnel have been obtained which will assure compliance with all laws regulating the~~
11 ~~compounding and distribution of drugs, the practice of pharmacy and the rules of the Board, a permit shall be issued~~
12 ~~by the Board attesting such registration.~~

13 (b) Separate dispensing areas operated by a Health Care Facility are not required to secure separate permits if those
14 dispensing areas are (a) contained in the same building as the permitted pharmacy or (b) contained in a building
15 located on property contiguous to the permitted pharmacy. However, even as to dispensing areas otherwise within
16 the coverage of this Paragraph, a separate permit is required for a dispensing area engaged in the routine activity of
17 dispensing drugs to or compounding drugs for a patient's use outside the Health Care Facility.

18 ~~(b) Exemptions.~~ (c) Nothing in these rules shall be construed to require the registration with the Board of those
19 ~~health care facilities~~ Health Care Facilities in which there occurs only the administration of drugs.

20 ~~(e) Separate Registration Required.~~ The dispensing of drugs from separate locations owned by a health care facility,
21 ~~such as satellite pharmacies, outside clinics, health maintenance organizations, or physician's offices owned by the~~
22 ~~health care facility shall require separate registration if any one of the following criteria exists:~~

23 (1) — The drugs dispensed at the location are ordinarily and customarily obtained from a source outside
24 of the health care facility;

25 (2) — The pharmacist manager is controlled and supervised from a source other than the health care
26 facility pharmacy; or

27 (3) — The routine activity at the location is dispensing drugs to outpatients.

28 ~~(d) Any pharmacy that provides compounding or dispensing services to one or more health care facilities for~~
29 ~~individual patient administration bearing any labeled name other than that under which it is registered shall require a~~
30 ~~separate registration.~~

31 ~~(e) Health care facilities which do not have a pharmacy permit shall secure their pharmaceutical services through a~~
32 ~~pharmacist holding a current license from the Board.~~

33 *History Note: Authority G.S. 90-85.6; 90-85.21;*

34 *Eff. April 1, 1983;*

35 *Amended Eff. May 1, 1997; May 1, 1989; March 1, 1984;*

36 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,*
37 *2017. 2017;*

