



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 .1415](#)

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 .1415, which deals with dispensing medications in health care facility (i.e., hospital) emergency departments. The existing rule permits an emergency department to dispense a 24-hour supply of drugs to patients being discharged from the emergency department. Regulated entities have approached the Board with concerns that limitation to a 24-hour supply poses problems with respect to (a) patients who may have difficulty getting additional prescriptions filled before the 24-hour supply expires (such as patients being discharged on weekends in rural areas) and (b) continuity of care for drugs that require longer courses of treatment and may create adverse effects in the case that they are interrupted. The proposed amendment would increase that limit to seven days. In addition, the proposed rule would clarify unclear language about whether a hospital emergency department may dispense drugs to discharged patients at a time when the hospital has an outpatient pharmacy open and available to dispense those drugs. 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 .1415 is proposed for amendment as follows:

2
3 **21 NCAC 46 .1415 MEDICATION IN HEALTH CARE FACILITY EMERGENCY DEPARTMENTS**

4 (a) In those ~~health care facilities~~ Health Care Facilities with having 24-hour ~~24-hour~~ outpatient pharmacy service,
5 all drugs dispensed to ~~outpatients-outpatients,~~ including emergency department patients, ~~patients-~~ must be dispensed
6 by the permitted pharmacy during times that it is open for outpatient pharmacy service. ~~a pharmacist.~~

7 (b) When the permitted pharmacy in the Health Care Facility is closed for outpatient service, ~~drugs are not~~
8 ~~otherwise available from a pharmacist,~~ drugs may be dispensed for use outside the emergency department by the
9 physician, registered nurse under physician supervision, or a person authorized to prescribe and dispense drugs
10 pursuant to G.S. 90-18.1 or 90-18.2 subject to the following:

- 11 (1) Drugs shall be dispensed only to a ~~registered~~ patient of the emergency department;
- 12 (2) The pharmacist-manager shall develop and supervise a system of control and accountability of all
13 drugs administered in, or dispensed from, ~~from~~ the emergency department;
- 14 (3) The pharmacist-manager ~~pharmacist manager, in conjunction with the committee responsible for~~
15 ~~policy in the emergency department,~~ shall develop an emergency department a formulary of of
16 prescription drugs that which may be dispensed from the emergency department for patients
17 receiving care in that department. This formulary shall consist of drugs of the nature and type to
18 meet the immediate needs of emergency department patients; ~~patients, and quantities in each~~
19 ~~container shall be limited to not more than a 24 hour supply or the smallest commercially-~~
20 ~~available quantity;~~
- 21 (4) The emergency department staff may dispense no more than a seven-day supply or the smallest
22 quantity prepackaged by the manufacturer for patient dispensing, whichever is greater;
- 23 (4)(5) Drugs shall be prepackaged in safety closure containers and shall be pre-labeled by the a
24 pharmacist to comply with Rule .1414(d)(4) of this Section. Prior to dispensing, the following
25 information shall be placed on the label:
- 26 (A) the name, address, and telephone number of the health care facility pharmacy;
- 27 (B) the dispensing date;
- 28 (C) the full name of patient;
- 29 (D) the generic or trade name, or in the absence of a brand name, the established name of the
30 product dispensed;
- 31 (E) directions for use to the patient;
- 32 (F) the name of physician prescribing and dispensing the product; and
- 33 (G) required precautionary or further accessory cautionary information as may be desirable
34 for proper use and safety to the patient;
- 35 (5) A perpetual record of dispensing of all drugs, including drug samples and starter packages, shall
36 be maintained as part of the pharmacy's records for three years. The pharmacist-manager or

1 designee shall verify the accuracy of these records at least once a month. The record shall contain
2 the following:

3 (A) the date dispensed;

4 (B) the patient's name;

5 (C) the physician's name; and

6 (D) the name, strength, dosage form, quantity, and dose of the drug dispensed.

7 (6) The physician shall sign all orders for medication within the time frame established by regulatory
8 agencies and health care facility policies and procedures.

9 (c) The physician, registered nurse under physician supervision, or person who is authorized to prescribe and
10 dispense drugs pursuant to G.S. 90-18.1 or 90-18.2 shall comply with all rules governing the dispensing of
11 medications including patient counseling as defined in 21 NCAC 46 .2504.

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13 *History Note: Authority G.S. 90-85.6; 90-18.1; 90-18.2; 90-85.21; 90-85.32; 90-85.33;*

14 *Eff. May 1, 1997;*

15 *Amended Eff. March 1, 2013;*

16 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3,*
17 *~~2017.~~ 2017;*

18 *Amended Eff. Nov. 1, 2024.*