REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Board of Pharmacy

RULE CITATION: 21 NCAC 46 .1401

DEADLINE FOR RECEIPT: Thursday, October 17, 2024.

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

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 email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Throughout the rule, has "dispensing area" been defined?

Also as to "dispensing areas" generally, does each area have its own pharmacist-manager? As I read G.S. 90-85.21(a), each pharmacy is required to have a pharmacist-manager. Reversing the logic, if each "dispensing area" has its own pharmacist-manager, would it not be a pharmacy?

In (b), line 16, please define "routine". How often must a dispensing area dispense drugs for outside use before it needs its own permit?

In (c), I assume that "administration" means literally handing someone their previously dispensed medication, and that "dispensing" means actually measuring it out, making sure there aren't contraindications, etc.? Are these terms defined?

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

Brian Liebman
Commission Counsel
Date submitted to agency: October 3, 2024

21 NCAC 46 .1401 is amended as published in 38:24 NCR 1649-50 as follows:

SECTION .1400 - HOSPITALS: OTHER HEALTH FACILITIES

21 NCAC 46 .1401 REGISTRATION AND PERMITS

(a) ~~Registration Required.~~ All Health Care Facilities ~~places~~ providing services ~~which embrace~~ within the practice of pharmacy shall apply for and receive a pharmacy permit ~~register with the North Carolina Board of Pharmacy~~ as 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 shall be on forms provided by the Board. If the Board is satisfied that proper facilities and adequately trained and properly licensed personnel have been obtained which will assure compliance with all laws regulating the compounding and distribution of drugs, the practice of pharmacy and the rules of the Board, a permit shall be issued by the Board attesting such registration.~~

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

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

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

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

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

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

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

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

History Note: *Authority G.S. 90-85.6; 90-85.21;*
Eff. April 1, 1983;
Amended Eff. May 1, 1997; May 1, 1989; March 1, 1984;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, ~~2017.~~ 2017;

Amended Eff. Nov. 1, 2024.

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: N.C. Board of Pharmacy

RULE CITATION: 21 NCAC 64 .1415

DEADLINE FOR RECEIPT: Thursday, October 17, 2024.

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

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 email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

In (b)(5), line 23, what is a "safety closure container"? I'm assuming we're talking about the traditional orange vials we all get when we go to the pharmacist, but not sure.

With respect to (b)(4) and (5), do the drugs pre-packaged by the manufacturer need to be enclosed in safety closure containers?

With respect to (b)(5), line 24, is an emergency department the location of an "auxiliary medication inventory"? Rule .1414(d)(4) covers "auxiliary medication inventories".

In (b)(6), line 35, what is a "perpetual record"? Does "perpetual" mean "three years" as on line 36?

In (b)(7), p.2, line 7, you need to strike through "(6)".

In (b)(7), line 7-8, what "regulatory agencies"?

Also in (b)(7), line 8, does "health care facility" need to be capitalized?

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

Brian Liebman
Commission Counsel
Date submitted to agency: October 3, 2024

21 NCAC 46 .1415 is amended as published in 38:24 NCR 1650-52 as follows:

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

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

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

(1) Drugs shall be dispensed only to a ~~registered~~ patient of the emergency department;

(2) The pharmacist-manager shall develop and supervise a system of control and accountability of all drugs administered in, or dispensed from, ~~from~~ the emergency department;

(3) The pharmacist-manager ~~pharmacist manager, in conjunction with the committee responsible for policy in the emergency department,~~ shall develop ~~an emergency department~~ a formulary of prescription drugs that ~~which~~ may be dispensed from the emergency department for patients receiving care in that department. This formulary shall consist of drugs of the nature and type to meet the immediate needs of emergency department patients; ~~patients, and quantities in each container shall be limited to not more than a 24 hour supply or the smallest commercially available quantity;~~

(4) The emergency department staff may dispense no more than a seven-day supply or the smallest quantity prepackaged by the manufacturer for patient dispensing, whichever is greater;

~~(4)~~ (5) Drugs shall be prepackaged in safety closure containers and shall be pre-labeled by ~~the~~ a pharmacist to comply with Rule .1414(d)(4) of this Section. Prior to dispensing, the following information shall be placed on the label:

(A) the name, address, and telephone number of the health care facility pharmacy;

(B) the dispensing date;

(C) the full name of patient;

(D) the generic or trade name, or in the absence of a brand name, the established name of the product dispensed;

(E) directions for use to the patient;

(F) the name of physician prescribing and dispensing the product; and

(G) required precautionary or further accessory cautionary information as may be desirable for proper use and safety to the patient;

~~(5)~~(6) A perpetual record of dispensing of all drugs, including drug samples and starter packages, shall be maintained as part of the pharmacy's records for three years. The pharmacist-manager or

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

(A) the date dispensed;

(B) the patient's name;

(C) the physician's name; and

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

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

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

History Note: *Authority G.S. 90-85.6; 90-18.1; 90-18.2; 90-85.21; 90-85.32; 90-85.33;*
Eff. May 1, 1997;
Amended Eff. March 1, 2013;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017. 2017;
Amended Eff. Nov. 1, 2024.