TITLE 21 – OCCUPATIONAL LICENSING BOARDS AND COMMISSIONS

CHAPTER 46 – BOARD OF PHARMACY

Notice *is hereby given in accordance with G.S. 150B-21.2 that the Board of Pharmacy intends to amend the rules cited as 21 NCAC 46 .2403 and .2502.*

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

Proposed Effective Date: *March 1, 2019*

Public Hearing:
Date: *January 15, 2019*
Time: *10:00 a.m.*
Location: *North Carolina Board of Pharmacy, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517*

Reason for Proposed Action:
21 NCAC 46 .*2043* - *The State Health Director has asked the Board to add over-the-counter nicotine replacement therapies to the list of drugs that can be dispensed by registered nurses in local health department clinics pursuant to this rule. The State Health Director intends to promote nicotine replacement therapies through its Tobacco Control and Prevention Branch. The State Health Director has indicated that, among other things, adding over-the-counter nicotine replacement to the list of drugs in this rule will more readily permit the Tobacco Control and Prevention Branch to implement its programs with the North Carolina Medicaid population. The Board is proposing amending the rule as requested by the State Health Director.*
21 NCAC 46 .2502 *– The board has proposed amending its pharmacist-manager rule to permit a person to continue to serve as pharmacist-manager at one pharmacy while also serving as the pharmacist-manager for a newly permitted pharmacy during the time that the newly permitted pharmacy has not yet begun providing pharmacy services to patients. The Board recognizes that newly permitted pharmacies will often take time to prepare to provide pharmacy services to patients. It wishes to accommodate that process by allowing a person to continue serving as a pharmacist-manager elsewhere while also preparing the newly permitted pharmacy to provide pharmacy services to patients.*

Comments may be submitted to: *Jay Campbell, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517, fax (919)246-1056, email jcampbell@ncbop.org*

Comment period ends: *January 15, 2019 at 10:00 a.m.*

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 after the adoption of the Rule. If the Rules Review Commission receives written and signed objections after the adoption of the Rule 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 facsimile transmission. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 919-431-3000.

Fiscal impact (check all that apply).
☐ **State funds affected**
☐ **Environmental permitting of DOT affected**
Analysis submitted to Board of Transportation
☐ **Local funds affected**
☐ **Substantial economic impact (≥$1,000,000)**
☐ **Approved by OSBM**
☒ **No fiscal note required by G.S. 150B-21.4**

SECTION .2400 - DISPENSING IN HEALTH DEPARTMENT

21 NCAC 46 .2403 DRUGS AND DEVICES TO BE DISPENSED
(a) Pursuant to the provisions of G.S. 90-85.34A(a)(3), prescription drugs and devices included in the following general categories may be dispensed by registered nurses in local health department clinics when prescribed for the indicated conditions:
(1) Anti-tuberculosis drugs, as recommended by the North Carolina Department of Health and Human Services in the North Carolina Tuberculosis Policy Manual (available at www.ncdhhs.gov), when used for the treatment and control of tuberculosis;
(2) Anti-infective agents used in the control of sexually-transmitted diseases as recommended by the United States Centers for Disease Control in the Sexually Transmitted Diseases Treatment Guidelines (available at www.cdc.gov);
(3) Natural or synthetic hormones and contraceptive devices when used for the prevention of pregnancy;
(4) Topical preparations for the treatment of lice, scabies, impetigo, diaper rash, vaginitis, and related skin conditions;

(5) Vitamin and mineral supplements;
(6) Opioid antagonists prescribed pursuant to G.S. 90-12.7; ~~and~~
(7) Epinephrine auto-injectors prescribed pursuant to G.S. 115C-375.2A; and ~~115C-375.2A.~~
(8) Over-the-counter nicotine replacement therapies.

(b) Regardless of the provisions set out in this Rule, no drug defined as a controlled substance by the United States Controlled Substances Act, 21 U.S. Code 801 through 904, or regulations enacted pursuant to that Act, 21 CFR 1300 through 1308, or by the North Carolina Controlled Substances Act, G.S. 90-86 through 90-113.8, may be dispensed by registered nurses pursuant to G.S. 90-85.34A.

History Note: *Authority G.S. 90-12.7; 90-85.6; 90-85.34A; 115C-375.2A.*

SECTION .2500 - MISCELLANEOUS PROVISIONS

21 NCAC 46 .2502 RESPONSIBILITIES OF PHARMACIST-MANAGER

(a) The pharmacist-manager shall assure that prescription legend drugs and controlled substances are safe and secure within the pharmacy.

(b) The pharmacist-manager employed or otherwise engaged to supply pharmaceutical services may have a flexible schedule of attendance but shall be present for at least one-half the hours the pharmacy is open or 32 hours a week, whichever is less. A pharmacist employee not meeting this requirement may serve as pharmacist-manager of the permit holder temporarily for a period not to exceed 90 days from the departure date of the previous pharmacist-manager, if the pharmacist employee is present at least 20 hours per week in the pharmacy.

(c) Whenever a change of ownership or change of pharmacist-manager occurs, the successor pharmacist-manager shall complete an inventory of all controlled substances in the pharmacy within 10 days. A written record of such inventory, signed and dated by the successor pharmacist-manager, shall be maintained in the pharmacy with other controlled substances records for a period of three years.

(d) The pharmacist-manager shall develop and implement a system of inventory record-keeping and control which will enable that pharmacist-manager to detect any shortage or discrepancy in the inventories of controlled substances at that pharmacy at the earliest practicable time.

(e) The pharmacist-manager shall maintain authority and control over any and all keys to the pharmacy and shall be responsible for the security of the pharmacy. A pharmacy shall be secured to prohibit unauthorized entry if no pharmacist will be present in the pharmacy for a period of 90 minutes or more.

(f) These duties are in addition to the specific duties of pharmacist-managers at institutional pharmacies and pharmacies in health departments as set forth in the Rules in this Chapter.

(g) A person shall not simultaneously serve as pharmacist-manager at more than one pharmacy, unless: ~~pharmacy at any one time except for~~

(1) the person is serving simultaneously as pharmacist-manager at pharmacies holding a limited service permit; or ~~pharmacies.~~
(2) the person is serving simultaneously as pharmacist-manager at two pharmacies holding full service permits, one of which is a newly permitted pharmacy that has not yet begun providing pharmacy services to patients. When the newly permitted pharmacy begins providing pharmacy services to patients or six months from the issuance of the new pharmacy permit, whichever comes sooner, the person must relinquish the other pharmacist-manager position and notify the Board of having done so.

(h) When a pharmacy is to be closed permanently, the pharmacist-manager shall inform the Board and the United States Drug Enforcement Administration of the closing, arrange for the proper disposition of the pharmaceuticals and return the pharmacy permit to the Board's offices within 10 days of the closing date. If possible, notice of the closing shall be given to the public by posted notice at the pharmacy at least 30 days prior to the closing date and 15 days after the closing date. Such notice shall notify the public that prescription files may be transferred to a pharmacy of the patient's or customer's choice during the 30 day period prior to the closing date. During the 30 day period prior to the closing date, the pharmacist-manager, and the pharmacy's owner (if the owner is other than the pharmacist-manager), shall transfer prescription files to another pharmacy chosen by the patient or customer, upon request. Absent specific instructions from the patient or customer, the pharmacist-manager, and the pharmacy's owner (if the owner is other than the pharmacist-manager), shall transfer prescription files to another pharmacy for maintenance of patient therapy and shall inform the public of such transfer by posted notice at the pharmacy for 15 days after the closing date, if possible. Controlled substance records shall be retained for the period of time required by law.

(i) If possible, the pharmacist-manager shall ensure that notice of the temporary closing of any pharmacy for more than 14 consecutive days is given to the public by posted notice at the pharmacy at least 30 days prior to the closing date, and 15 days after the closing date. Such notice shall notify the public that prescription files may be transferred to a pharmacy of the patient's or customer's choice during the 30 day period prior to the closing date. During the 30 day period prior to the closing date, the pharmacist-manager, and the pharmacy's owner (if the owner is other than the pharmacist-manager), shall transfer prescription files to another pharmacy chosen by the patient or customer, upon request.

(j) The pharmacist-manager shall prepare a plan to safeguard prescription records and pharmaceuticals and minimize the interruption of pharmacy services in the event of a natural disaster such as hurricane or flood.

(k) The pharmacist-manager shall separate from the dispensing stock all drug products more than six months out of date.

(l) The pharmacist-manager shall report to the Board of Pharmacy information that reasonably suggests that there is a probability that a prescription drug or device dispensed from a location holding a permit has caused or contributed to the death of a patient or customer. This report shall be filed in writing on a form provided by the Board within 14 days of the owner representative or pharmacist-manager's becoming aware of the event. The pharmacist-manager shall retain all documents, labels, vials, supplies, substances and internal investigative reports relating to the event. All such items shall be made available to the Board upon request.

(m) The Board shall not disclose the identity of a pharmacist-manager who makes a report under Paragraph (l) of this Rule, except as required by law. No report made under Paragraph (l) of this Rule shall not be released except as required by law.
(n) In any Board proceeding, the Board shall consider compliance with Paragraph (l) of this Rule as a mitigating factor and noncompliance with Paragraph (l) of this Rule as an aggravating factor.
(o) The pharmacist-manager shall ensure that all starter doses of medication supplied to doctors' offices from the pharmacy are accompanied by written materials advising the patient that such doses of medication may be supplied by any pharmacy. Starter doses shall be limited to a 24 hour dose supply per patient.

Authority G.S. 90-85.6; 90-85.21; 90-85.25; 90-85.26; 90-85.32.