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 adopt the rule cited as 21 NCAC 46 .1616 and amend the rules cited as 21 NCAC 46 .1317, .1703, .1706, and .2502.*

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

Proposed Effective Date: *September 1, 2021*

Public Hearing:
Date: *July 20, 2021*
Time: *10:00 a.m.*
Location: *The public hearing will be held remotely. The public can participate on Teams at https://tinyurl.com/3wn9x3xc or may call 336-604-5350, conference ID 560 519 380#.*

Reason for Proposed Action: *Under existing rules of the Board of Pharmacy, the Board may grant limited service permits to pharmacies that operate on limited hours in an institutional setting (i.e., pharmacies in health care facilities). The only current distinction in the rules between a limited service permit and a regular permit is that a pharmacist may serve on an ongoing basis as the pharmacist-manager of multiple pharmacy permits only if those permits are limited service permits. As a practical matter, there has been an ad hoc development of the use of limited service permits in other settings where limited pharmaceutical services are provided.*

The proposed adoption of Rule .1616 would codify a more expansive view of limited service permits that would include those pharmacies rendering services where the Board believes that services may be safely provided by pharmacist-managers who serve multiple pharmacies. Proposed Rule .1616 would further allow for the pharmacist-manager to be present at the limited service permit for less time than required at regular pharmacy permits, with the amount of time depending upon the amount necessary to safely supervise each type of permit. It further would allow the pharmacist-manager to designate an assistant pharmacist-manager to help exercise supervision due to the unique nature of these limited service permits.

Proposed changes to other rules (Rules .1317, .1703, .1706 and .2502) are principally intended to conform those rules to the new Rule .1616. In addition: (1) Rule .1317 will be generally updated to remove definitions that are no longer used elsewhere in the rules and, in some cases, to substitute similar terms that are used elsewhere in the rules; (2) Rule .1703 will be updated to provide that the pharmacist-manager does not need to personally package drugs to be dispensed by nurse practitioners and physician assistants; (3) Rule .2502 will clarify some pharmacist-manager duties already provided in the rules; and (4) Rule .2502(o) will also be removed as contrary to current pharmacy laws.

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

Comment period ends: *July 20, 2021 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. Does any rule or combination of rules in this notice create an economic impact? Check all that apply.
☐ **State funds affected**
☐ **Local funds affected**
☐ **Substantial economic impact (>= $1,000,000)**
☐ **Approved by OSBM**
☒ **No fiscal note required**

SECTION .1300 - GENERAL DEFINITIONS

21 NCAC 46 .1317 DEFINITIONS
~~The definitions of various terms~~ Terms used in this Chapter and ~~are found in~~ G.S. 90, Article 4A, are defined ~~and~~ as follows, unless otherwise defined in G.S. 90, Article 4A: ~~follows:~~

(1) Ambulation assistance equipment. ~~Assistance Equipment.~~ Devices that aid in walking, excluding canes, crutches, and walkers.

(2) Approved school or college of pharmacy. ~~School or College of Pharmacy.~~ A school or college of pharmacy accredited by the American Council on Pharmaceutical Education. ~~Education, or a foreign school with a professional pharmacy degree program of at least five years approved by the Board pursuant to G.S. 90-85.13.~~

~~(3) Auxiliary Drug Inventory. A secure, segregated, supplementary source for drugs to be used solely for the purpose of providing adequate drug availability when the pharmacy is closed or the pharmacist is unavailable.~~

~~(4) Board. As defined in G.S. 90-85.3(b).~~

~~(5) Certified technician. A technician who has passed a pharmacy technician certification board exam, or its equivalent, that has been approved by the Board according to the rules in this Chapter.~~

~~(6) Consultant Pharmacist. A licensed pharmacist who, in collaboration with the supervising physician and nurse practitioner or assistant to the physician, develops a retrospective drug utilization review program that:~~

~~(a) reviews the appropriateness of the choice of medication(s) for the patient and the patient's therapeutic regimen, including choice of medication, dose, frequency, and route of administration;~~

~~(b) identifies and resolves therapeutic duplication in the patient's medication regimen; and~~

~~(c) considers patient-specific medication contraindications.~~

~~The consultant pharmacist holds himself available for consultation in person, by telephone, or by other means of direct communication at all times when drugs are dispensed.~~

~~(7)~~(3) Diagnostic equipment. Equipment used to record physiological information while a person goes about normal daily living or while asleep in order to document a disease process. Early pregnancy tests (EPTs), thermometers, glucose meters, and cholesterol equipment are not included as diagnostic equipment.

~~(8)~~(4) Drug regimen review or drug use review. ~~Pharmaceutical care assessment. An onsite~~ A review of a patient's ~~or resident's~~ record by a licensed pharmacist that involves interpretation and evaluation of the drug therapy and other pharmaceutical care services to achieve intended medication outcomes and minimize negative effects of drug therapy.

~~(9) Duplicate as used in G.S. 90-85.24. Any license, permit, or registration issued or reissued by the Board that is identical to a previously issued license, permit, or registration, including a permit reissued due to a change in pharmacist-manager.~~

~~(10) Emergency Drugs. Those drugs whose prompt use and immediate availability are generally regarded by physicians as essential in the proper treatment of unforeseen adverse changes in a patient's health or well-being.~~

~~(11)~~(5) Employee. A person who is or would be considered an employee under the North Carolina Workers' Compensation Act. This definition applies to locations both within and outside of this State holding pharmacy or device and medical equipment permits and without regard to the number of persons employed by the permit holder.

~~(12) Executive Director. The Secretary-Treasurer and Executive Director of the Board.~~

~~(13)~~(6) Graduate of an approved school of college of pharmacy. ~~Approved School or College of Pharmacy.~~ A person who has received an undergraduate professional degree in pharmacy from an approved school or college of pharmacy. ~~pharmacy, or a person who has graduated from a foreign professional school of pharmacy and has successfully completed the Foreign Pharmacy Graduate Equivalency Examination offered by the National Association of Boards of Pharmacy and the Test of English as a Foreign Language.~~

~~(14) HMES. Home medical equipment supplier.~~

~~(15)~~(7) Health Care Facility. ~~Any organization~~ One of the following organizations whose primary purpose is to provide a physical environment for patients to obtain health care services: ~~services. This shall include:~~

(a) a hospital;
(b) a long-term care facility;
(c) a mental health facility;
(d) a drug abuse treatment center;
(e) a penal institution; or
(f) a hospice.

~~(16)~~(8) Health Care Facility Pharmacy. A pharmacy permitted by the Board that provides services to patients of a Health Care Facility.

~~(17) Indulgence in the Use of Drugs. The use of narcotic drugs or other drugs affecting the central nervous system or the use of intoxicating beverages to an extent as to deprive the user of reasonable self-control or the ability to exercise such judgment as might reasonably be expected of an average prudent person.~~

~~(18)~~(9) Internet pharmacy. ~~Pharmacy.~~

(a) A pharmacy that maintains an Internet web site for the purpose of selling or distributing prescription drugs; or

(b) A pharmacy that uses the ~~internet,~~ Internet, either itself, or through agreement with a third party, to communicate with or obtain information from patients; uses such communication or information, in whole or in part, to solicit, fill or refill prescriptions; or otherwise uses such communication or information, in whole or in part, to engage in the practice of pharmacy. ~~pharmacy as defined in G.S. 90-85.3(r).~~

Notwithstanding Sub-items (a) and (b) above, a pharmacy shall not be deemed an Internet pharmacy if it maintains an Internet web site for the following purposes only:

(i) To post mere advertisements that do not attempt to facilitate, directly or through agreement with a third party, an actual transaction involving a prescription drug;

(ii) To allow a patient to communicate a request for a refill of a legitimate prescription originally filled by the pharmacy that maintains the Internet web site;

(iii) To allow a customer to research drug interactions and clinical pharmacology information; or

(iv) To allow a patient to send an electronic mail message to a pharmacist licensed in North Carolina.

~~(19) Limited Service Pharmacy Permit. A pharmacy permit issued by the Board to an applicant who wishes to render in an institutional setting pharmaceutical services not limited to scope and kind but to time and conditions under which such services are rendered.~~

~~(20) Medication Therapy Management Services and Related Functions. Services and functions included in the practice of pharmacy as part of monitoring, recording and reporting drug therapy and device usage.~~

~~(21) Medication Administration Record. A record of drugs administered to a patient.~~

~~(22)~~(10) Medication Order. An order for a ~~prescription drug or other medication or a~~ drug, device or medical equipment for a patient from a person authorized by law to prescribe them. ~~medications.~~

~~(23)~~(11) Mobility equipment. Devices that aid a person in self-movement, other than walking, including manual or power wheelchairs and scooters.

(12) North Carolina resident or resident of North Carolina. Any patient who is a temporary or permanent resident of the State of North Carolina or who is present in the State of North Carolina at the time a drug, device, or medical equipment is dispensed to that person.

~~(24)~~(13) Oxygen and respiratory care equipment. Equipment or devices used to administer oxygen or other legend drugs, maintain viable airways or monitor cardio-respiratory conditions or events, including the following:

(a) compressed medical gases;

(b) oxygen concentrators;

(c) liquid oxygen;

(d) nebulizers;

(e) compressors;

(f) aerosol therapy devices;

(g) portable suction machines;

(h) nasal continuous positive airway pressure (CPAP) machines;

(i) Bi-phasic positive pressure devices (BiPAP);

(j) infant monitors, such as apnea monitors and cardio-respiratory monitors;

(k) positive and negative pressure mechanical ventilators; and

(l) pulse oximeters.

~~(25)~~(14) Patient medication profile, patient profile or pharmacy profile. ~~Medication Profile.~~ A list of all ~~prescribed~~ medications prescribed for or dispensed to a patient.

~~(26) Pharmacist. Any person within the definition set forth in G.S. 90-85.3(p), including any druggist.~~

~~(27)~~(15) Pharmacist-Manager. The person who accepts responsibility for the operation of a pharmacy in conformance with all statutes and rules pertinent to the practice of pharmacy and distribution of drugs by signing the permit application, its renewal or addenda thereto.

~~(28) Pharmacy. Any place within the definition set forth in G.S. 90-85.3(q), including any apothecary or drugstore.~~

~~(29)~~(16) Pharmacy Intern. Any person who is registered with the Board under the internship program of the Board to acquire pharmacy experience or enrolled in approved academic internship programs. A pharmacy intern working under a pharmacist preceptor or supervising pharmacist may, while under supervision, perform all acts constituting the practice of pharmacy.

~~(30) Place of residence. Any place used as an individual's temporary or permanent home.~~

~~(31) President. The President of the Board.~~

~~(32)~~(17) Rehabilitation environmental control equipment. Equipment or devices that permit a person with disabilities to control his or her immediate surroundings.

~~(33) Rehabilitation Services. Services and equipment required to maintain or improve functional status and general health as prescribed by the physician which are uniquely specified for each individual's lifestyle. The people involved in this process include the patient, caregiver, physician, therapist, rehabilitation equipment supplier and others who impact on the individual's life style and endeavors.~~

~~(34) Signature. A written or electronic signature or computerized identification code.~~

~~(35) Two Years of College Work. Attendance at a college accredited by an accrediting agency recognized by the United States Department of Education for two academic years of not fewer than eight and one-half months each and the completion of work for credit leading to a baccalaureate degree or its equivalent and that would permit the student to advance to the next class.~~

~~(36)~~(18) Undergraduate professional degree in pharmacy. ~~Professional Degree in Pharmacy. A B.S. or Pharm. D. degree.~~ A Bachelor of Science in Pharmacy or a Doctor of Pharmacy degree.

~~(37) Vice-President. The Vice-President of the Board.~~

Authority G.S. 90-18.1; 90-18.2; 90-18.4; 90-85.3; 90-85.3A; 90-85.6; ~~90-85.8;~~ 90-85.13; 90-85.14; 90-85.15; 90-85.15A; 90-85.21; 90-85.21A; 90-85.22; 90-85.26; 90-85.26A; 90-85.32; 90-85.33; 90-85.34; 90-85.34A; 90-85.38; 90-85.40; 90-85.41; 90-85.44. ~~90-85.40.~~

SECTION .1600 - LICENSES AND PERMITS

21 NCAC 46 .1616 LIMITED SERVICE PERMITS

(a) The following permits are described in this Chapter as "limited service permits:"

(1) auxiliary medication inventories permitted and operating in health care facilities pursuant to Rule .1414(d) of this Chapter;
(2) automated dispensing or drug supply devices permitted and operating in health care facilities pursuant to Rule .1419 of this Chapter;
(3) facilities where drugs are dispensed only by nurse practitioners or physician assistants pursuant to Section .1700 of this Chapter;
(4) county health departments or other governmental entities providing local health services under G.S. 130A-34 where drugs are dispensed only by registered nurses and only pursuant to G.S. 90-85.34A and Section .2400 of this Chapter;
(5) county health departments or other governmental entities providing local health services under G.S. 130A-34 that engage in dispensing beyond that set out in G,S. 90-85,34A and Section .2400 of this Chapter;
(6) free clinics, as defined in G.S. 90-85.44(a)(6); or
(7) critical access hospitals, as defined in G.S. 131E-76.

(b) A pharmacist-manager for a limited service permit may designate one assistant pharmacist-manager but is not required to do so. An assistant pharmacist-manager is responsible for exercising all of the responsibilities of a pharmacist-manager when the assistant pharmacist-manager is present but the pharmacist-manager is not present at the limited service permit. If the pharmacist-manager chooses to designate an assistant pharmacist-manager, the pharmacist-manager shall notify the Board on the limited service permit application and, in writing, within 15 days of any change in the designation. Notwithstanding the pharmacist-manager's designation of an assistant pharmacist-manager, the pharmacist-manager shall be responsible for ensuring the pharmacy's compliance with all statutes, rules and standards at all times.

(c) For limited service permits, the pharmacist-manager attendance requirements set out in Rule .2502(b) of this Chapter are modified only as set forth herein:

(1) For limited service permits described in Subparagraphs (a)(1) and (2) of this Rule, either the pharmacist-manager or the assistant pharmacist-manager must perform an in-person, on-site visit at least once per calendar quarter to inspect the permit, review the operations of the permit with the persons involved in accessing them and ensure that the permits are operated in compliance with all applicable state and federal laws.
(2) For limited service permits described in Subparagraphs (a)(3) and (4) of this Rule, either the pharmacist-manager or the assistant pharmacist-manager must perform an in-person, on-site visit at least once per week to inspect the permit, review the operations of the permit with the persons involved in dispensing and ensure that the permits are operated in compliance with all applicable state and federal laws.
(3) For limited service permits described in Subparagraphs (a)(5), (6) and (7) of this Rule, either the pharmacist-manager or the assistant 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 of the hours the pharmacy is open or 20 hours a week, whichever is less. For the limited service permits described in Subparagraphs (a)(5) and (6) of this Rule, a licensed pharmacist must be present when the pharmacy is open as described in Rule .2502(e) of this Chapter. For the limited service permits described in Subparagraph (a)(7) of this Rule, the limited service may operate in the absence of a pharmacist only as set out in Rule .1413 of this Chapter.
(4) The limited service permit may name a temporary pharmacist-manager or assistant pharmacist-manager for a period not to exceed 90 days from the departure date of the previous pharmacist-manager or assistant pharmacist-manager. The temporary pharmacist-manager or assistant pharmacist-manager must accept the responsibilities of that position and must be present as set forth in this Rule. A limited service permit may not operate for a period of more than 30 days without a pharmacist employed or otherwise engaged as a permanent or temporary pharmacist-manager who has signed the permit for that pharmacy.

(d) A person may serve as the pharmacist-manager or the assistant pharmacist-manager for multiple limited service permits, and may serve as the pharmacist-manager or assistant pharmacist-manager for limited service permits in addition to serving as the pharmacist-manager for a maximum of one permit other than a limited service permit. A person may serve multiple limited permits only if that person is able to fulfill all of that person's duties under state and federal law.

(e) Other than as expressly set forth in this section, limited service permits and their pharmacy personnel must follow all requirements of state and federal law. This Rule does not replace or modify the requirements that the pharmacist-manager provide oversight and supervision as provided elsewhere in these Rules.

Authority G.S. 90-18.1; 90-18.2; 90-85.6; 90-85.21; 90-85.33; 90-85.34; 90-85.34A.

SECTION .1700 - DRUGS DISPENSED BY NURSE OR PHYSICIAN'S ASSISTANT

21 NCAC 46 .1703 DRUGS TO BE DISPENSED

(a) The nurse practitioner may dispense any and all drugs that the nurse practitioner is authorized by law to prescribe.

(b) The physician assistant may dispense any and all drugs that the physician assistant is authorized by law to prescribe.

~~(c) The pharmacist shall prepare a plan to ensure that there are adequate amounts of each of the drugs dispensed by a nurse practitioner or physician assistant, and that such drugs are properly stored and packaged.~~

~~(d)~~(c) All drugs dispensed by a nurse practitioner or physician assistant must be dispensed from a place holding a current pharmacy permit from the Board as required by G.S. 90-85.21.

~~(e)~~(d) The ~~consulting~~ pharmacist-manager or another licensed pharmacist working under the pharmacist-manager's supervision shall be available for consultation in person, by telephone, or other means of direct communication at all times when drugs are dispensed, including to perform drug regimen review for patients as needed. ~~dispensed.~~

~~(f)~~(e) All drugs dispensed pursuant to G.S. 90-18.1(c), 90-18.2(c) and the rules of this Section shall be packaged, labeled, and otherwise dispensed in compliance with state and federal law, and records of dispensing shall be kept in compliance with state and federal law. The pharmacist-manager shall be responsible for compliance with these laws at all times, regardless of whether the pharmacist-manager is present at the time of dispensing. ~~All drugs dispensed by the nurse practitioner or physician assistant shall be prepackaged in safety closure containers and shall be appropriately prelabeled (including necessary auxiliary labels) by the pharmacist with all information required by law except the name of the patient and the directions for use. The name of the patient and directions for use of the drugs shall be placed on the label by the nurse practitioner or physician assistant at the time it is delivered to the patient or his agent.~~

Authority G.S. 90-18.1; 90-18.2; 90-85.6; 90-85.21; 90-85.26. ~~90-85.6.~~

21 NCAC 46 .1706 RETROSPECTIVE REVIEW AND CONSULTATION

During the weekly in-person, on-site visit required by Rule .1616(c)(2) of this Chapter, if not more frequently, the pharmacist-manager or assistant pharmacist-manager shall retrospectively perform a drug regimen review of all drugs dispensed by a nurse practitioner or physician assistant. During this review, the pharmacist-manager or assistant pharmacist-manager shall:

(a) review the appropriateness of the choice of medication(s) for each patient and the patient's therapeutic regimen, including choice of medication, dose, frequency, and route of administration;

(b) identify and resolve therapeutic duplication in each patient's medication regimen; and

(c) consider patient-specific medication contraindications.

~~All drugs dispensed by a nurse practitioner or physician assistant shall be retrospectively reviewed by a pharmacist on a weekly basis. The reviewing pharmacist may advise and consult with the dispensing nurse practitioner, physician assistant, or supervising physician about potential drug therapy concerns which may result from:~~

~~(1) therapeutic duplication;~~

~~(2) drug-disease contraindication;~~

~~(3) interactions between or among drugs, including serious interactions with prescription or over-the-counter drugs;~~

~~(4) incorrect drug dosage or duration of drug treatment;~~

~~(5) interactions between drugs and allergies; and~~

~~(6) clinical abuse or misuse.~~

Authority G.S. 90-18.1; 90-18.2; 90-85.6.

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~~ Except as expressly provided in Rule .1616 of this Chapter, 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 temporary pharmacist-manager of the permit holder 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. A pharmacy may not operate for a period of more than 30 days without a pharmacist employed or otherwise engaged as a permanent or temporary pharmacist-manager who has signed the permit for that 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 the 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 that 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 access ~~keys~~ to the pharmacy and shall be responsible for the security of the pharmacy. Except as provided in Rules .1413(c) and .1616(c)(1) and (2) of this Chapter, a pharmacist must be present at both the opening and closing of the pharmacy. If no pharmacist will be present in the pharmacy for a period of 90 minutes or more between the opening and closing of the pharmacy, ~~more,~~ the pharmacy shall be secured to prohibit unauthorized entry.

(f) These duties shall be in addition to the ~~specific~~ duties of pharmacist-managers ~~at institutional pharmacies and pharmacies in health departments~~ as set forth in the other rules in this Chapter.

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

(1) ~~the person is serving simultaneously as pharmacist-manager at pharmacies holding a limited service permit; or~~ any additional permits beyond that one permit is a limited service permit as provided in Rule .1616 of this Chapter; or

(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 occurs sooner, the person shall relinquish the former 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 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. 90-18.1; 90-18.2; 90-85.6; 90-85.15A; 90-85.21; 90-85.21A; 90-85.25; 90-85.26; 90-85.32; 90-85.33; 90-85.34; 90-85.34A. ~~90-85.32.~~