REQUEST FOR TECHNICAL CHANGE

AGENCY: Board of Pharmacy

RULE CITATION: All Rules Submitted

DEADLINE FOR RECEIPT: Monday, October 11, 2021

***NOTE:* This request when viewed on computer extends 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 call our office to inquire concerning the staff recommendation.

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

On the Submission for Permanent Rule form, please sign Box 11.

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

Amanda J. Reeder
Commission Counsel
Date submitted to agency: September 27, 2021

REQUEST FOR TECHNICAL CHANGE

AGENCY: Board of Pharmacy

RULE CITATION: 21 NCAC 46 .1317

DEADLINE FOR RECEIPT: Monday, October 11, 2021

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 call our office to inquire concerning the staff recommendation.

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

In (1), what is an example of this equipment? Does your regulated public know what is included, rather than what is excluded?

In Item (7), Page 2, line 19, please underline "One of the following organizations" As this was underline in the Register, do not show it as a change; simply do it.

In Sub-Item (9)(b)(i), Page 3, line 10, do you need "mere" here?

In Sub-Item (9)(b)(ii), line 12, what is a "legitimate" prescription? Does your regulated public know?

In Item (10), line 26, please insert a comma after "device"

In Item (11), line 28, please delete the comma after "self-movement"

In Item (12), line 32, please insert a comma after "device"

In Item (13), line 34, does your regulated public know what "viable" airway means?

Also on line 34, please insert a comma after "airways"

In Item (14), Page 4, line 11, please insert a comma after "profile"

In Item (15), line 16, please insert a comma after "renewal"

In Item (17), line 25, please underline "(17)" As this was correctly published in the Register, please do not show it as a change; simply do it.

In the History Note, line 5, why are you citing to G.S. 90-85.14?

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

Amanda J. Reeder
Commission Counsel
Date submitted to agency: September 27, 2021

21 NCAC 46 .1317 is amended with changes as published in 35:22 NCR 2440 as follows:

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) an assisted living facility;

(f) an ambulatory surgical 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~~ each 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 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.~~

History Note: *Authority G.S. 90-85.3; 90-85.6; ~~90-85.8;~~ 90-85.13; 90-85.14; 90-85.15; 90-85.21; 90-85.21A; 90-85.22; 90-85.26; 90-85.32; 90-85.33; 90-85.34; 90-85.38; 90-85.40;*
Eff. May 1, 1989;
Amended Eff. March 1, 2013; February 1, 2007; March 1, 2004; April 1, 1999; May 1, 1997; September 1, 1995; September 1, 1993; October 1, 1990; January 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017; ~~2017.~~
Amended Eff. November 1, 2021.

REQUEST FOR TECHNICAL CHANGE

AGENCY: Board of Pharmacy

RULE CITATION: 21 NCAC 46 .1616

DEADLINE FOR RECEIPT: Monday, October 11, 2021

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 call our office to inquire concerning the staff recommendation.

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

On the Submission for Permanent Rule form, Box 3, please check that this is an adoption.

In (a)(5), line 16, what do you mean by "beyond that"? How is this allowed?

Also on line 16, please relace the commas in "G.S." and "90-85.34A" with periods.

In (b), lines 20-21, I am simply asking – do you need to retain "but is not required to do so"?

On line 21, since they can only appoint one, should "An" before "assistant" be "The"?

On line 21, consider replacing "is" with "shall be"

On line 22, I think you should replace "but" with "and"

On line 24, are the contents of this application what are listed in G.S. 90-85.21?

On line 27, please insert a comma after "rules"

Also on line 27, what "standards" are these?

In (c)(1), line 33, please insert a comma after "them"

On line 34, assuming you mean "NC" please capitalize "State" Please note the same change for (c)(2), Page 2, line 2, (d), line 21, and (e), line 24.

In (c)(2), line 1, please insert a comma after "dispensing"

In (c)(3), line 3, please insert a comma after "(6)"

In (d), what are you saying on lines 18-20? On line 18, you refer to "multiple" limited service permits and on line 20, you state a pharmacist-manager may work for one other limited service permit. What is the intent? Is it to allow the assistant pharmacist-manager to work at more than two places and limit the pharmacist-manager to two places? I think this can be clarified.

Amanda J. Reeder
Commission Counsel
Date submitted to agency: September 27, 2021

In (e), line 23, what do you mean by "expressly"? Do you need it here?

Also on line 23, what do you mean by "section"? If you mean Section .1600, please capitalize the term. If you mean instead to refer to only Rule .1616, please state "this Rule"

On line 25, consider replacing "these Rules" with "this Chapter."

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

21 NCAC 46 .1616 is adopted with changes as published in 35:22 NCR 2440 as follows:

21 NCAC 46 .1616 LIMITED SERVICE PERMITS

(a) The following pharmacy practice locations are eligible to apply for [~~permits are described in this Chapter as~~] "limited service [~~permits:"~~] permits" whose operations are modified by the provisions set forth in this Rule:

(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 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.

History Note: *Authority G.S. 90-18.1(c); 90-18.2; 90-85.6; 90-85.21; 90-85.33; 90-85.34;*
Eff. November 1, 2021.

REQUEST FOR TECHNICAL CHANGE

AGENCY: Board of Pharmacy

RULE CITATION: 21 NCAC 46 .1703

DEADLINE FOR RECEIPT: Monday, October 11, 2021

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 call our office to inquire concerning the staff recommendation.

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

In (d), line 12, will "another pharmacist" include an assistant pharmacist-manager (as created in Rule .1616)?

In (e), line 15, please insert a comma after "90-18.2(c)"

On lines 16 and 17, please capitalize "State" if you mean only NC.

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

Amanda J. Reeder
Commission Counsel
Date submitted to agency: September 27, 2021

21 NCAC 46 .1703 is amended as published in 35:22 NCR 2440 as follows:

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.~~

History Note: *Authority G.S. 90-18.1; 90-18.2; 90-85.6;*
Eff. April 1, 1983;
Amended Eff. April 1, 1999; May 1, 1997; May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, ~~2017.~~ 2017;
Amended Eff. November 1, 2021.

21 NCAC 46 .1706 is amended as published in 35:22 NCR 2440 as follows:

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.~~

History Note: *Authority G.S. 90-18.1; 90-18.2; 90-85.6;*
Eff. April 1, 1999;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017; ~~2017.~~
Amended Eff. November 1, 2021.

21 NCAC 46 .2502 is amended as published in 35:22 NCR 2440 as follows:

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;

(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.~~

History Note: *Authority G.S. 90-85.6; 90-85.21; 90-85.21A; 90-85.25; 90-85.26; 90-85.32;*
Eff. May 1, 1989;
Amended Eff. April 1, 2006; February 1, 2005; August 1, 2002; December 1, 2001; April 1, 2001; April 1, 1999; July 1, 1996; March 1, 1992; October 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017;
Amended Eff. March 1, ~~2019.~~ 2019; November 1, 2021.