CHAPTER 46 - BOARD OF PHARMACY

SECTION .0100 - ORGANIZATION OF THE BOARD

21 NCAC 46 .0101 GENERAL PURPOSE OF THE BOARD
21 NCAC 46 .0102 ELECTION OF THE BOARD
21 NCAC 46 .0103 MEETINGS OF THE BOARD
21 NCAC 46 .0104 QUORUMS
21 NCAC 46 .0105 OFFICE OF THE BOARD
21 NCAC 46 .0106 FISCAL YEAR

History Note: *Authority G.S. 90-56; 90-57; 90-58;*
Eff. February 1, 1976;
Readopted Eff. September 22, 1977;
Amended Eff. August 16, 1981;
Repealed Eff. April 1, 1983.

SECTION .0200 - GENERAL DEFINITIONS

21 NCAC 46 .0201 SCOPE OF DEFINITIONS
21 NCAC 46 .0202 BOARD: OFFICERS
21 NCAC 46 .0203 DRUGS
21 NCAC 46 .0204 POISONS
21 NCAC 46 .0205 NONPOISONOUS DOMESTIC REMEDIES
21 NCAC 46 .0206 PATENT OR PROPRIETARY PREPARATION
21 NCAC 46 .0207 PHARMACY OR DRUGSTORE
21 NCAC 46 .0208 ORIGINAL DRUGSTORE PERMIT
21 NCAC 46 .0209 PERSON
21 NCAC 46 .0210 PHARMACIST OR DRUGGIST
21 NCAC 46 .0211 ASSISTANT PHARMACIST
21 NCAC 46 .0212 PHARMACY EXTERN
21 NCAC 46 .0213 PHARMACY INTERN
21 NCAC 46 .0214 LICENSED PHARMACIST INTERN
21 NCAC 46 .0215 DULY ACCREDITED SCHOOL OR COLLEGE OF PHARMACY
21 NCAC 46 .0216 GRADUATE OF AN ACCREDITED SCHOOL OR COLLEGE OF PHARMACY
21 NCAC 46 .0217 TWO YEARS COLLEGE TRAINING
21 NCAC 46 .0218 GROSS IMMORALITY
21 NCAC 46 .0219 HABITUAL INDULGENCE
21 NCAC 46 .0220 IMMEDIATE SUPERVISION
21 NCAC 46 .0221 TEMPORARY ABSENCE
21 NCAC 46 .0222 PHARMACEUTICAL SERVICES
21 NCAC 46 .0223 COMPOUNDING
21 NCAC 46 .0224 DISPENSING
21 NCAC 46 .0225 ADMINISTERING
21 NCAC 46 .0226 HOSPITAL PHARMACY
21 NCAC 46 .0227 PRESCRIPTION

History Note: *Authority G.S. 90-57; 90-61; 90-61.1; 90-65; 90-71; 90-72; 90-73; 90-75;*
Eff. February 1, 1976;
Readopted Eff. September 22, 1977;
Repealed Eff. April 1, 1983.

SECTION .0300 - HOSPITALS: OTHER HEALTH FACILITIES

21 NCAC 46 .0301 DEFINITION: OTHER PLACE
21 NCAC 46 .0302 REGISTRATION AND PERMITS
21 NCAC 46 .0303 PERSONNEL: EQUIPMENT: AND INSPECTION
21 NCAC 46 .0304 PHARMACIST-MANAGER
21 NCAC 46 .0305 SUPERVISION: SCHEDULE OF ATTENDANCE BY PHARMACIST
21 NCAC 46 .0306 HEALTH CARE FACILITIES NOT EMPLOYING A PHARMACIST
21 NCAC 46 .0307 SUPERVISION OF DRUGS IN AREAS OUTSIDE A PHARMACY
21 NCAC 46 .0308 ACCESS TO DRUG STOCKS: RECORDS: EMERGENCY DRUG KITS
21 NCAC 46 .0309 MEDICATION IN HOSPITAL EMERGENCY DEPARTMENTS
21 NCAC 46 .0310 PRACTITIONERS OF MEDICINE EXCEPTED
21 NCAC 46 .0311 MINIMAL STANDARDS FOR PHARMACY SERVICE
21 NCAC 46 .0312 FEDERAL AND STATE STATUTES CONTROL

History Note: *Authority G.S. 90-18.1; 90-57; 90-75;*
Eff. February 1, 1976;
Readopted Eff. September 22, 1977;
Repealed Eff. April 1, 1983.

SECTION .0400 - EXAMINATIONS: ADMISSION REQUIREMENTS

21 NCAC 46 .0401 APPLICATION
21 NCAC 46 .0402 AGE
21 NCAC 46 .0403 EXPERIENCE IN PHARMACY
21 NCAC 46 .0404 EDUCATION
21 NCAC 46 .0405 EXAMINATION
21 NCAC 46 .0406 RULES OF EXAMINATION CONDUCT
21 NCAC 46 .0407 PARTIAL EXAMINATION

History Note: *Authority G.S. 90-57; 90-61; 90-61.1;*
Eff. February 1, 1976;
Readopted Eff. September 22, 1977;
Amended Eff. January 1, 1982; October 21, 1981; January 15, 1981; May 4, 1980;
Repealed Eff. April 1, 1983.

SECTION .0500 - LICENSES AND PERMITS

21 NCAC 46 .0501 PHARMACY OR DRUGSTORE PERMITS
21 NCAC 46 .0502 FAILURE TO COMPLY: PENALTY
21 NCAC 46 .0503 DRUGSTORES IN TOWNS OF LESS THAN 800 POPULATION
21 NCAC 46 .0504 ABSENCE FROM PRACTICE

History Note: *Authority G.S. 90-57; 90-71; 90-75;*
Eff. February 1, 1976;
Readopted Eff. September 22, 1977;
Amended Eff. May 4, 1980;
Repealed Eff. April 1, 1983.

21 NCAC 46 .0505 RECIPROCAL LICENSURE

History Note: *Authority G.S. 90-57; 90-64;*

Eff. February 1, 1976;
Readopted Eff. September 22, 1977;
Amended Eff. August 16, 1981; January 15, 1981;
Repealed Eff. January 1, 1982.

21 NCAC 46 .0506 LICENSE BY RECIPROCITY

History Note: *Authority G.S. 90-57; 90-64;*
Eff. March 1, 1982;
Repealed Eff. April 1, 1983.

SECTION .0600 - DRUGS DISPENSED BY NURSE OR PHYSICIAN'S ASSISTANT

21 NCAC 46 .0601 DISPENSING BY REGISTERED NURSE OR PHYSICIAN'S ASSISTANT
21 NCAC 46 .0602 DISPENSING SUPERVISED BY LICENSED PHARMACIST
21 NCAC 46 .0603 DRUGS TO BE DISPENSED
21 NCAC 46 .0604 PREPACKAGING OF DRUG PRODUCTS DISPENSED
21 NCAC 46 .0605 RECORDS OF DISPENSING

History Note: *Authority G.S. 90-18.1; 90-57; 90-75;*
Eff. February 1, 1976;
Readopted Eff. September 22, 1977;
Repealed Eff. April 1, 1983.

SECTION .0700 - FORMS

21 NCAC 46 .0701 DEFINITION
21 NCAC 46 .0702 APPLICATION FOR PHARMACIST'S LICENSE
21 NCAC 46 .0703 APPLICATION FOR PHARMACY PERMIT
21 NCAC 46 .0704 RENEWAL OF PHARMACIST'S LICENSE
21 NCAC 46 .0705 REPLACEMENT OF CERTIFICATES
21 NCAC 46 .0706 RECIPROCITY DATA QUESTIONNAIRE
21 NCAC 46 .0707 APPLICATION FOR RECIPROCITY
21 NCAC 46 .0708 REGISTRATION FOR PRACTICAL PHARMACY TRAINING
21 NCAC 46 .0709 PRACTICAL PHARMACY EXPERIENCE
21 NCAC 46 .0710 CERTIFICATE OF EXPERIENCE OUTSIDE NORTH CAROLINA
21 NCAC 46 .0711 CERTIFICATE OF GRADUATION

History Note: *Authority G.S. 90-57; 90-61; 90-64; 90-66; 90-75;*
Eff. February 1, 1976;
Readopted Eff. September 22, 1977;
Repealed Eff. April 1, 1983.

SECTION .0800 - ADMINISTRATIVE HEARING PROCEDURES

21 NCAC 46 .0801 RIGHT TO HEARING
21 NCAC 46 .0802 REQUEST FOR HEARING
21 NCAC 46 .0803 GRANTING OR DENYING HEARING REQUESTS
21 NCAC 46 .0804 NOTICE OF HEARING
21 NCAC 46 .0805 WHO SHALL HEAR CONTESTED CASES
21 NCAC 46 .0806 PETITION FOR INTERVENTION
21 NCAC 46 .0807 TYPES OF INTERVENTION

21 NCAC 46 .0808 DISQUALIFICATION OF HEARING OFFICERS

History Note: Authority G.S. 1A-1, Rule 24; 90-57; 90-65; 150A-2(2); 150A-23(a); 150A-23(2); 150A-32;
Eff. February 1, 1976;
Readopted Eff. September 22, 1977
Amended Eff. August 16, 1981;
Repealed Eff. April 1, 1983.

SECTION .0900 - ADMINISTRATIVE HEARINGS: DECISIONS: RELATED RIGHTS AND PROCEDURES

21 NCAC 46 .0901 FAILURE TO APPEAR
21 NCAC 46 .0902 SIMPLIFICATION OF ISSUES
21 NCAC 46 .0903 SUBPOENAS
21 NCAC 46 .0904 FINAL DECISIONS IN ADMINISTRATIVE HEARINGS
21 NCAC 46 .0905 PROPOSALS FOR DECISIONS

History Note: Authority G.S. 90-57; 150A-25(a); 150A-33(5); 150A-34(a); 150A-43; 150A-72;
Eff. February 1, 1976;
Readopted Eff. September 22, 1977;
Amended Eff. August 16, 1981;
Repealed Eff. April 1, 1983.

SECTION .1000 - RULEMAKING PROCEDURES

21 NCAC 46 .1001 PETITIONS
21 NCAC 46 .1002 NOTICE
21 NCAC 46 .1003 HEARINGS
21 NCAC 46 .1004 EMERGENCY RULES
21 NCAC 46 .1005 DECLARATORY RULINGS
21 NCAC 46 .1006 RULES AND REGULATIONS SEVERABLE

History Note: Authority G.S. 90-57; 150A-12; 150A-16; 150A-17;
Eff. February 1, 1976;
Readopted Eff. September 22, 1977;
Amended Eff. August 16, 1981;
Repealed Eff. April 1, 1983.

SECTION .1100 - ELECTIONS

21 NCAC 46 .1101 BOARD OF PHARMACY ELECTIONS: COMPOSITIONS AND DUTIES
21 NCAC 46 .1102 ELIGIBILITY TO VOTE
21 NCAC 46 .1103 GEOGRAPHIC REPRESENTATIONS
21 NCAC 46 .1104 COMMITTEE ON NOMINATIONS
21 NCAC 46 .1105 NOMINATION BY PETITION
21 NCAC 46 .1106 CONSENT TO NOMINATION
21 NCAC 46 .1107 BALLOTS: CASTING AND COUNTING

History Note: Authority G.S. 90-55(a),(b);

Eff. January 1, 1982;
Repealed Eff. April 1, 1983.

SECTION .1200 - ORGANIZATION OF THE BOARD

21 NCAC 46 .1201 GENERAL PURPOSE OF THE BOARD

(a) The purpose of the Board is to regulate the practice of pharmacy in North Carolina in order to safeguard and protect the life and health of the people of North Carolina, and in order to promote the public welfare.
(b) The Board regulates the practice of pharmacy:
(1) by determining the qualifications of persons seeking to practice pharmacy and authorizing persons who have met the statutory requirements to so practice; and
(2) by enforcing the provisions of laws governing the practice of pharmacy and places for rendering pharmaceutical services, and those duly enacted rules designed to ensure a high degree of competency in the practice of pharmacy.

History Note: *Authority G.S. 90-85.2; 90-85.6;*
Eff. April 1, 1983;
Amended Eff. May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1202 ELECTION OF OFFICERS OF THE BOARD

Election of officers of the Board shall be held in May of each year.

History Note: *Authority G.S. 90-85.6; 90-85.8;*
Eff. April 1, 1983;
Amended Eff. May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1203 MEETINGS OF THE BOARD

The Board shall meet at least twice each year at a place designated by the Board for the purpose of examining candidates for a license to practice pharmacy in North Carolina and may hold such other examination meetings as it may deem appropriate, and in addition may regularly meet at other times for the purpose of transacting business and holding hearings. Special meetings of the Board may be called by the president, the executive director, or two or more members of the Board when deemed necessary, and notice shall be given to each member of the Board of the time and place of such special meetings and the business to be transacted at such meetings.

History Note: *Authority G.S. 90-85.6; 90-85.9;*
Eff. April 1, 1983;
Amended Eff. May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1204 OFFICE OF THE BOARD

History Note: *Authority G.S. 90-85.6;*
Eff. April 1, 1983;
Amended Eff. November 1, 2003; July 1, 1996; May 1, 1989;
Repealed Eff. October 1, 2010.

21 NCAC 46 .1205 FISCAL YEAR

The fiscal year of the Board shall be from October 1st through September 30th of the following calendar year.

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

21 NCAC 46 .1206 FEES

The fees provided for in G.S. 90-85.24 as maximum fees which the Board is entitled to charge and collect are hereby established as the fees for each of the items in G.S. 90-85.24.

History Note: *Authority G.S. 90-85.6; 90-85.24;*
Eff. November 1, 1983;
Amended Eff. May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1207 DEVICE AND MEDICAL EQUIPMENT COMMITTEE

(a) The device and medical equipment committee shall consist of the following:

(1) a representative of the medical equipment suppliers;
(2) a representative of the medical oxygen suppliers;
(3) a representative of the rehabilitation technology suppliers; and
(4) two Board members.

(b) Each of the members of the device and medical equipment committee shall be appointed by the Board. Device and medical equipment permit holders may provide input in these appointments. The representative must practice in the area for which he or she is nominated, but need not practice exclusively in that area. In case of death, resignation, or removal from the committee, the Board shall fill the vacancy with a representative who meets the criteria for the position.

History Note: *Authority G.S. 90-85.6; 90-85.22;*
Eff. April 1, 2020.

SECTION .1300 - GENERAL DEFINITIONS

21 NCAC 46 .1301 SCOPE OF DEFINITIONS
21 NCAC 46 .1302 BOARD: OFFICERS
21 NCAC 46 .1303 PHARMACY PERMIT
21 NCAC 46 .1304 DRUGGIST
21 NCAC 46 .1305 PHARMACY INTERN
21 NCAC 46 .1306 DULY APPROVED SCHOOL OR COLLEGE OF PHARMACY
21 NCAC 46 .1307 GRADUATE/APPROVED SCHOOL/COLLEGE OF PHARMACY
21 NCAC 46 .1308 TWO YEARS COLLEGE WORK
21 NCAC 46 .1309 INDULGENCE IN THE USE OF DRUGS
21 NCAC 46 .1310 SUPERVISION
21 NCAC 46 .1311 INSTITUTIONAL PHARMACY
21 NCAC 46 .1312 PHARMACIST MANAGER
21 NCAC 46 .1313 LIMITED SERVICE PHARMACY PERMIT
21 NCAC 46 .1314 APOTHECARY
21 NCAC 46 .1315 DRUGSTORE
21 NCAC 46 .1316 UNDERGRADUATE PROFESSIONAL DEGREE IN PHARMACY

History Note: *Authority G.S. 90-85.3; 90-85.6; 90-85.8; 90-85.13; 90-85.15; 90-85.15(b); 90-85.21; 90-85.38(3); 90-85.40(a);*
Eff. April 1, 1983;
Amended Eff. January 1, 1985; March 1, 1984; April 1, 1983;
Repealed Eff. May 1, 1989.

21 NCAC 46 .1317 DEFINITIONS

Terms used in this Chapter and G.S. 90, Article 4A, are defined as follows, unless otherwise defined in G.S. 90, Article 4A:

(1) "Ambulation assistance equipment" means devices that aid in walking, excluding canes, crutches, and walkers.

(2) "Approved school or college of pharmacy" means a school or college of pharmacy accredited by the Accreditation Council for Pharmacy Education ("ACPE") through its PharmD Program Accreditation Standards. It does not include any accreditation, certification, or other designation through the ACPE's International Services Program.

(3) "Diagnostic equipment" means 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.

(4) "Drug regimen review" or "drug use review" means a review of a patient'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.

(5) "Employee" means 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.

(6) "Graduate of an approved school or college of pharmacy" means a person who has received an undergraduate professional degree in pharmacy from an approved school or college of pharmacy.

(7) "Health Care Facility" means one of the following organizations whose primary purpose is to provide a physical environment for patients to obtain health care services:

(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;
(g) a penal institution; or
(h) a hospice.

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

(9) "Internet pharmacy" means:

(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, 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.

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

(i) To post 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 valid 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.

(10) "Medication Order" means an order for a drug, device, or medical equipment for a patient from a person authorized by law to prescribe them.

(11) "Mobility equipment" means 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" includes not just any patient who is domiciled in the State of North Carolina, but also any patient who is present in the State of North Carolina at the time a drug, device, or medical equipment is dispensed to that person.

(13) "Oxygen and respiratory care equipment" means 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.

(14) "Patient medication profile," "patient profile," or "pharmacy profile" means a list of all medications prescribed for or dispensed to a patient.

(15) "Pharmacist-Manager" means 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.

(16) "Pharmacy Intern" means 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.

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

(18) "Undergraduate professional degree in pharmacy" means a Bachelor of Science in Pharmacy or a Doctor of Pharmacy degree.

History Note: *Authority G.S. 90-85.3; 90-85.6; 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;
Amended Eff. October 1, 2022; November 1, 2021.

SECTION .1400 - HOSPITALS: OTHER HEALTH FACILITIES

21 NCAC 46 .1401 REGISTRATION AND PERMITS

(a) Registration Required. All places providing services which embrace the practice of pharmacy shall register with the North Carolina Board of Pharmacy as provided in 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) Exemptions. Nothing in these rules shall be construed to require the registration with the Board of those 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.

21 NCAC 46 .1402 SUPERVISION OF DRUGS IN AREAS OUTSIDE OF PHARMACY
21 NCAC 46 .1403 INSTITUTIONAL PHARMACY DRUG INVENTORIES AND EMERGENCY KITS
21 NCAC 46 .1404 MEDICATION IN INSTITUTIONAL EMERGENCY DEPARTMENTS

History Note: *Authority G.S. 90-18.1; 90-18.2; 90-85.6; 90-85.21;*
Eff. April 1, 1983;
Amended Eff. April 1, 1992; May 1, 1989; March 1, 1984;
Repealed Eff. May 1, 1997.

21 NCAC 46 .1405 STANDARDS FOR PHARMACY SERVICE

History Note: *Authority G.S. 90-85.2; 90-85.6;*
Eff. March 1, 1984;
Repealed Eff. May 1, 1989.

21 NCAC 46 .1406 AUTOMATIC STOP ORDERS

History Note: *Authority G.S. 90-85.2; 90-85.3(r); 90-85.6;*
Eff. March 1, 1984;
Amended Eff. May 1, 1989;
Repealed Eff. May 1, 1997.

21 NCAC 46 .1407 INSTITUTIONAL FORMULARY

History Note: *Authority G.S. 90-85.2; 90-85.3(r); 90-85.6;*
Eff. March 1, 1984;
Repealed Eff. May 1, 1989.

21 NCAC 46 .1408 INSTITUTIONAL DISCHARGE MEDICATION OPTION

History Note: *Authority G.S. 90-85.6; 90-85.32;*
Eff. March 1, 1984;
Amended Eff. May 1, 1989;
Repealed Eff. May 1, 1997.

21 NCAC 46 .1409 RESEARCH PARTICIPATION

History Note: *Authority G.S. 90-85.3(r); 90-85.6; 90-85.34;*
Eff. March 1, 1984;
Repealed Eff. May 1, 1989.

21 NCAC 46 .1410 PERSONNEL

(a) The health care facility pharmacy must be directed by a legally qualified pharmacist, hereinafter referred to as the pharmacist-manager, who shall be responsible for meeting the requirements set forth by Federal and State law, this Section, 21 NCAC 46 .2502, and other applicable Rules of the Board. The pharmacist-manager shall be thoroughly familiar with the specialized functions of health care facility pharmacy practice. The pharmacist-manager shall be an employee of the health care facility or contracted for by the health care facility in which the pharmacy is located.
(b) The pharmacist-manager shall be assisted by a sufficient number of pharmacists and supportive personnel to operate such pharmacy competently, safely, and to meet the needs of the patients of the health care facility.
(c) The pharmacist-manager shall ensure that an adequate number of qualified and trained pharmacists are employed. The pharmacist- manager shall develop and implement written policies and procedures to specify the duties to be performed by such pharmacists.
(d) The pharmacist-manager shall ensure that a sufficient number of qualified, trained, and adequately supervised supportive personnel are employed to provide technical services, as well as ensuring that all such functions and activities are performed competently, safely, and without risk of harm to patients. The relationship between the supervising pharmacist and the supportive personnel shall be such that the pharmacist is fully aware of and responsible for all activities involved in the preparation and dispensing of medications prior to release to the patient, including the maintenance of appropriate records.
(e) Secretarial and clerical support shall be provided to assist with record keeping, report submission and other administrative duties.

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

21 NCAC 46 .1411 RESPONSIBILITIES OF THE PHARMACIST-MANAGER

(a) The pharmacist-manager shall establish written procedures for the safe and effective distribution of pharmaceutical products. Procedures shall be reviewed annually to assure they reflect current practice in the facility. A copy of such procedures shall be available in the pharmacy.
(b) The pharmacist-manager is responsible for the safe and effective distribution of, control over and accountability for drugs, including intravenous and irrigation solutions. The pharmacist-manager may delegate responsibilities to other health care facility staff for ordering, distributing, and accounting for pharmaceutical materials to achieve this purpose. Whenever there is a violation of the rules in this Section, the facility's pharmacy permit is subject to action by the Board. In addition to the requirements of 21 NCAC 46 .2502, the pharmacist-manager is responsible for:

(1) the development of policies and procedures for the compounding, admixture, labeling, and dispensing of parenteral medications in the health care facility, including relevant education and training of all pharmacy and nursing personnel involved in the preparation of parenteral medications;
(2) the establishment of specifications or use of compendia specifications for procurement of all pharmaceuticals, including drugs, chemicals, and biologicals used in direct patient care, subject to approval of the appropriate committee of the health care facility;
(3) participation in development and maintenance of a drug formulary when required by the health care facility;
(4) participation in those aspects of pharmaceutical care that affect drug distribution and control;
(5) preparing, packaging, compounding and labeling all drugs;
(6) assuring that drugs are dispensed only by a pharmacist or other persons allowed by law to dispense and that supportive pharmacy personnel are directed and supervised in compliance with all applicable laws and regulations;
(7) the development and implementation of policies and procedures to ensure that discontinued drugs; outdated drugs; drugs recalled; containers with worn, illegible, or missing labels; or products that are otherwise unusable are returned to the pharmacy for disposition in compliance with all applicable laws and regulations;
(8) maintaining records and reports required by law to ensure patient health, safety and welfare;
(9) developing and implementing policies and procedures that effectively address the safeguarding and handling of all drugs and devices, as defined in G.S. 90-85.3(e), throughout the health care facility, or other locations where legend drug products are transferred, including medications that originate from a source outside the facility. When discrepancies in controlled substance counts are identified:

(A) they shall be reviewed, and a report of this action, including steps taken to prevent recurrence, where possible, shall be provided to the pharmacist-manager within 24 hours of occurrence. This report shall be maintained by the pharmacist-manager; and

(B) they shall be reported to the Board and the Drug Enforcement Administration in compliance with all applicable laws and regulations;

(10) developing and implementing policies and procedures to ensure that auxiliary medication inventories are inspected in accordance with the pharmacy's policies;

(11) all drugs and devices dispensed by the pharmacy as defined in G.S. 90-85.3(e) that are ordered for and used within the health care facility; and

(12) maintaining policies and procedures regarding drug samples and patient's personal medications.

History Note: *Authority G.S. 90-85.6; 90-85.21; 90-85.32;*
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.

21 NCAC 46 .1412 PHYSICAL REQUIREMENTS

A health care facility pharmacy shall have sufficient floor space allocated to it to ensure that drugs are prepared in sanitary, well lighted, and enclosed places. It shall have equipment and physical facilities for proper compounding, dispensing, and storage of drugs, including parenteral preparations. In addition to the requirements of Section .1600 of this Chapter, the equipment and physical facilities shall include the following:

(1) Dispensing areas;

(2) Compounding areas that comply with Section .2800 of this Chapter;

(3) Receiving and storage areas;

(4) Packaging and repackaging areas;

(5) Office space sufficient to allow for administrative functions without interference with the safe compounding and dispensing of medications and security of the pharmacy;

(6) Storage. All drugs shall be stored in designated areas within the pharmacy or decentralized pharmacy sufficient to provide sanitation to prevent contamination, moisture control, and security to prevent access from unauthorized personnel. Controlled substances shall be stored in compliance with applicable Federal and State laws and regulations. Alcohol and flammables shall be stored in areas that shall meet basic local building code requirements for the storage of volatile substances and all other laws, ordinances, or regulations that may apply; and

(7) Security. All areas occupied by the health care facility pharmacy, to include auxiliary drug supplies and unit dose carts, shall remain secured at all times.

History Note: *Authority G.S. 90-85.6; 90-85.21; 90-85.32;*
Eff. May 1, 1997;
Amended Eff. January 1, 2015; March 1, 2013;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1413 ABSENCE OF PHARMACIST

(a) When a health care facility pharmacy is not open 24 hours a day, seven days a week, arrangements shall be made in advance by the pharmacist-manager for provision of drugs and pharmaceutical care to the medical staff, other authorized personnel, and patients of the health care facility by use of an "on call" pharmacist accessible to the facility during all absences, and auxiliary medical inventories as described in Rule .1414(d) of this Section. In addition, one or both of the options in Subparagraphs (a)(1) and (2) may be authorized by the pharmacist-manager to assure access to drugs and pharmaceutical care in the absence of a pharmacist:

(1) a contractual arrangement with another health care facility, pharmacy, or pharmacist; or

(2) a nurse trained and authorized by the pharmacist-manager to remove drugs or devices from the pharmacy in the absence of a pharmacist. Entry into the pharmacy in the absence of a pharmacist shall occur only if the drug needed is not in the auxiliary medication inventory. The pharmacist-manager shall maintain a current list of authorized persons and document the initial orientation, continuing education, and quality control processes on an ongoing basis. The pharmacist-manager shall maintain a list of restricted medications that shall not be taken from the pharmacy and may only be removed after contacting the "on call" pharmacist to

verify the appropriateness and accuracy of the medication order and medication removed from the pharmacy at the time of removal. For medications not on the restricted list, an "on call" pharmacist must be accessible for questions by the authorized nurse. Within 24 hours, a pharmacist shall verify the accuracy and appropriateness of the medication order and the medication removed from the pharmacy.

(b) A record of drugs or devices removed from auxiliary medication inventories or from pharmacy inventory shall be maintained for three years in the health care facility in compliance with all applicable laws and regulations. The pharmacist-manager shall at least quarterly verify the accuracy of the records.

(c) Supportive personnel approved by the pharmacist-manager may be present in the pharmacy at other than regular service hours to perform clerical, repackaging and distributive functions according to written policies and procedures if the drugs so handled are not permitted to leave the pharmacy until all work performed has been checked and certified as being correct by the pharmacist.

(d) Only drugs in unit-of-use packaging shall be removed from the auxiliary medication inventory or from the pharmacy; they shall be used for administration to a specific patient only, in amounts sufficient to meet the needs for immediate therapeutic requirements. Controlled substances may be stocked and removed from auxiliary medication inventories; controlled substances may not be removed from the pharmacy in the absence of a pharmacist. Drugs shall be pre-labeled by the pharmacist with drug name, strength, lot number and expiration date. A copy of written orders for new medications shall be provided to the pharmacy.

History Note: *Authority G.S. 90-85.6; 90-85.21; 90-85.32; 90-85.33; 90-85.34;*
Eff. May 1, 1997;
Amended Eff. March 1, 2013; August 1, 2000;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1414 DRUG DISTRIBUTION AND CONTROL

(a) MEDICATION ORDERS.

(1) Pharmacists shall dispense medications from a health care facility pharmacy only upon receipt of a medication order. A mechanism shall be in place to verify the authenticity of the medication order. Oral orders shall be recorded immediately and signed within the time frame established by regulatory agencies and health care facility policies and procedures.

(2) All medication orders shall be received and reviewed by a pharmacist and shall contain the:

(A) patient's name, location and other identifying information such as history or medical records number;

(B) medication name, strength, dosage form, route of and directions for administration. In the absence of a facility policy on interpretation of routes of administration, the route of administration must be specified;

(C) discernible quantity to be dispensed. Medical orders issued from a health care facility shall, in the absence of a different indicated quantity or facility policy, be deemed to authorize dispensing of a 30-day supply;

(D) date the order was written; and

(E) prescriber's signature as set out in Subparagraph (a)(1) of this Rule (may include electronic signature or verification).

(3) The health care facility pharmacy and the pharmacist-manager shall ensure that medication orders for patients requiring continuous drug therapy are entered into a patient medication profile, either manual or automated. The medication profile shall contain the:

(A) patient's name, location, and clinical data required for safe dispensing and administration of medication orders, such as age, height, weight, sex, and allergies;

(B) medication name, strength, dosage form, route of, and directions for administration;

(C) medication start date;

(D) medication discontinuance date; and

(E) identification of pharmacist responsible for or verifying technician entry of the medication order.

(4) Abbreviations used in medication orders shall be agreed to, jointly adopted, and published by the medical, nursing, pharmacy, and medical records staff of the health care facility.

(5) A method to protect the health care facility patients from indefinite, open-ended medication orders must be provided. The prescriber shall be notified that the order shall be stopped before such action takes place by one or more of the following:

(A) the routine monitoring of patient's drug therapy by a pharmacist;
(B) a health care facility-approved, drug class-specific, automatic stop order policy covering those drug orders not specifying a number of doses or duration of therapy; or
(C) a health care facility-approved automatic cancellation of all medication orders after a predetermined time interval unless rewritten by the prescriber.

(6) Health care facilities that credential practitioners for prescribing privileges within the facility shall provide the health care facility pharmacy with credentialing information annually or immediately upon discharge or when privileges are suspended or terminated.

(b) DISPENSING. In health care facilities with 24 hour pharmacy services, all dispensing shall be done by a pharmacist. In health care facilities without 24 hour pharmacy services, Rules .1413 and .1417 of this Section apply in the absence of a pharmacist.

(c) LABELING.

(1) The health care facility pharmacy and the pharmacist dispensing the drug shall ensure that all drugs dispensed from within a health care facility pharmacy are labeled and identified up to the point of administration;

(2) When a drug is added to a parenteral admixture, it shall be labeled with a distinctive supplementary label indicating the name and amount of the drug added, expiration date, and expiration time, if applicable. For admixtures prepared outside the health care facility pharmacy, the pharmacist-manager shall develop policies and procedures for preparation and labeling.

(d) AUXILIARY MEDICATION INVENTORIES.

(1) The pharmacist-manager of the health care facility pharmacy shall, in consultation with medical staff, develop a list of drugs and devices that may be stocked in auxiliary medication inventories (which may include patient care unit medication inventories, ancillary drug cabinet inventories, and emergency kits) located at the health care facility. This list shall include those drugs and devices that may be required to meet the immediate therapeutic needs of patients, but that are not reasonably available from the health care facility pharmacy in sufficient time to prevent prolonged discomfort or risk of harm to the health care facility's patients.

(2) The pharmacist-manager of the health care facility pharmacy shall develop, implement, and monitor compliance with policies and procedures that ensure auxiliary medication inventories are accessed only in compliance with all applicable laws and regulations and only by licensed health-care professionals or those authorized by North Carolina law to administer medications. If an auxiliary medication inventory is accessed in an unauthorized manner, the health care facility personnel who become aware of the access shall notify the health care facility pharmacy's pharmacist-manager.

(3) An auxiliary medication inventory shall contain drugs and devices only in amounts sufficient to meet immediate therapeutic needs of patients.

(4) Drugs and devices contained in an auxiliary medication inventory shall be labeled with the name, strength, lot number, manufacturer, and expiration date. A listing of the drugs and devices contained within an auxiliary medication inventory, including the name, strength, and quantity of each, shall be attached.

(5) When an auxiliary medication inventory is accessed, the health care facility personnel who become aware of the access shall provide a copy of both the record of withdrawal and patient medication order to the health care facility pharmacy's pharmacist-manager. The record of withdrawal shall contain:
(A) the date of the removal;
(B) the name, strength, dosage form, and quantity of drug or device removed;
(C) the name of the patient for whom the drug or device was ordered; and
(D) the name or other identification of the authorized person who removed the drug or device.

(6) The health care facility's pharmacist-manager shall ensure that auxiliary medication inventories are reviewed on a schedule set by the health care facility pharmacy's policies to ensure the purity, potency, and integrity of drugs and devices contained within;

(7) An auxiliary medication inventory containing controlled substances must comply with 10A NCAC 26E .0408.

(e) RESERVED.

(f) RESERVED.

(g) RESERVED.

(h) RESERVED.

(i) RESERVED.

(j) RECORDS.

(1) The pharmacist-manager shall, in addition to the requirements for preserving prescription orders as set forth in G.S. 90-85.26, develop a system of daily accountability for medication compounding and dispensing that permits the identification of the responsible pharmacists and pharmacy technicians. Readily retrievable records of accountability shall be maintained for at least 30 days. This system shall identify all personnel who perform these activities and the pharmacist responsible for:
   (A) interpretation and appropriateness of new medication orders;
   (B) profile entry of new medication orders;
   (C) dispensing of new medication orders including stat doses;
   (D) daily cart fills;
   (E) intravenous admixtures;
   (F) compounded medications; and
   (G) assessing the quality of pharmacy procedures for preparation and release of drugs and devices for replenishment of auxiliary medication inventories and automated dispensing devices in locations outside the pharmacy.

(2) Upon notification of medication errors resulting from the administration of an incorrect medication or dose, the pharmacist-manager shall document the medication error. Documentation shall include chronological information and include documentation on health care facility forms. These documents shall be archived in a readily retrievable manner, open for inspection, for a period of three years.

(3) Upon notification of information that reasonably suggests that there is a probability a prescription drug or device dispensed from a location holding a permit has caused or contributed to the death of a patient (see 21 NCAC 46 .2502(k)), the pharmacist-manager shall retain all documents, labels, vial, supplies, substances, and internal investigative reports relating to the event. All such items shall be maintained by the health care facility, accessible to the pharmacist-manager, and open to the Board of Pharmacy.

(4) The pharmacist-manager shall maintain records of ordering, receiving, dispensing, or transfer of controlled substances. These records shall include the following:
   (A) Invoices or other documents verifying the ordering and receipt of controlled substances;
   (B) Perpetual inventories of controlled substances transferred to auxiliary medication inventories and automated dispensing devices. These inventories shall record the transfer date; the location transferred to; the identity of the drug; the strength, dosage form, and quantity transferred; and the transferring pharmacist's name;
   (C) Records of disposition of a controlled substance prepared for a patient but not used, including documentation of the details of the destruction or other disposition and identification of the individuals involved in that destruction or other disposition;
   (D) A record of controlled substances dispensed directly to the patient to include the patient's name; date dispensed; dispensing pharmacist's name; name, strength, dosage form, and quantity of the drug dispensed. The records shall also document drugs returned and credited; and
   (E) A perpetual inventory on all controlled substances awaiting destruction or return to a vendor.

(5) Automated systems may be used to collect and store information required by Subparagraph (j)(4) of this Rule provided such system allows for the immediate retrieval of original medication order information and dispensing history consistent with criteria cited in 21 CFR .1306.

(6) With the exception of Subparagraph (j)(l) of this Rule, all records required by this Section shall be maintained for a period of three years. Such records shall be archived in a uniform manner, retrievable to the pharmacy within 48 hours, and open for review, copying, or seizure by a member or designated employee of the Board.

History Note: *Authority G.S. 90-85.6; 90-85.21; 90-85.32; 90-85.33; 90-85.34;*
Eff. May 1, 1997;
Amended Eff. March 1, 2013; February 1, 2005; April 1, 2003; April 1, 1999; August 1, 1998.
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

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

(a) In those health care facilities having 24 hour outpatient pharmacy service, all drugs dispensed to outpatients including emergency department patients must be dispensed by a pharmacist.

(b) When 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 the emergency department;

(3) The pharmacist-manager, in conjunction with the committee responsible for policy in the emergency department, shall develop an emergency department formulary 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, and quantities in each container shall be limited to not more than a 24 hour supply or the smallest commercially-available quantity;

(4) Drugs shall be prepackaged in safety closure containers and shall be pre-labeled by the 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) 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) 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.

21 NCAC 46 .1416 REPACKAGING

(a) Drugs which are prepackaged from within a health care facility pharmacy for subsequent dispensing or administration shall be labeled to include:

(1) the generic or trade name, strength, and quantity of drug;

(2) identification of the manufacturer, and lot or control number;

(3) the expiration date of the drug being repackaged; and

(4) cautionary notations, if applicable.

(b) A batch number assigned by the pharmacy may be placed on the label in lieu of the manufacturer's name and lot number, provided that the pharmacy maintains a readily retrievable record which identifies, by batch number, the manufacturer, manufacturer's expiration date, and lot number of the drug.

(c) The pharmacy shall have and use facilities, personnel, operational practices, packaging material, and control procedures to assure that the purity, integrity, safety, and effectiveness of the drugs are not affected by such repackaging. All repackaging must be performed by or under the supervision of a pharmacist.

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

21 NCAC 46 .1417 REMOTE MEDICATION ORDER PROCESSING SERVICES

History Note: *Authority G.S. 90-85.6; 90-85.21; 90-85.21A; 90-85.26; 90-85.32; 90-85.34;*
Eff. February 1, 2006;
Amended Eff. December 1, 2015; March 1, 2013;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017;
Repealed Eff. March 1, 2022.

21 NCAC 46 .1418 SUPERVISION OF UNIT DOSE MEDICATION SYSTEMS

(a) The purpose of this Section is to set out requirements in the event that pharmacists elect to supervise designated pharmacy technicians' validation of stocking and prepackaging functions in acute care hospital pharmacy practice settings as a means of facilitating pharmacists' delivery of clinical services.

(b) A Hospital's pharmacist-manager is responsible for the oversight of all validation of floor stock and unit dose distribution systems, and that responsibility may not be delegated pursuant to 21 NCAC 46 .1411. In the event that the Hospital's pharmacist-manager elects to utilize Validating Technicians in the filling of floor stock and unit dose distribution systems, the pharmacist-manager shall develop written policies and procedures that:

(1) permit a Validating Technician to validate only the following functions of other registered pharmacy technicians in filling floor stock and unit dose distribution systems for inpatients in a Hospital:
  (A) stocking of patient care unit medication inventories;
  (B) stocking of ancillary drug cabinet inventories;
  (C) stocking of automated dispensing or drug supply devices;
  (D) stocking of emergency kits; and
  (E) prepackaging of prescription drugs within the Hospital pharmacy;
(2) establish the parameters for pharmacist supervision of pharmacy technician validation functions;
(3) establish facility-specific training for pharmacy technician validation functions;
(4) establish an ongoing evaluation and assessment program to ensure that pharmacy technician validation functions are performed safely and accurately; and
(5) establish a recordkeeping system that shall permit the identification of the Validating Technician who performs activities authorized by this Rule. Readily retrievable records generated by this system shall be maintained for the period of time specified in 21 NCAC 46 .1414(j)(1) and (2).

(c) With respect to compounded or admixed prescription drugs (whether sterile or non-sterile), a Validating Technician may validate the filling of floor stock and unit dose distribution systems only after a pharmacist has verified that the compounded or admixed prescription drugs have been prepared correctly.

(d) This Rule does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.

(e) Validating Technician. For the purposes of this Rule, a Validating Technician shall be a pharmacy technician who:

(1) is registered with the Board and trained as specified in G.S. 90-85.15A;
(2) is a certified technician;
(3) holds either:
  (A) an associate's degree in pharmacy technology conferred by either an institution within the North Carolina Community College System or System;
  (B) an associate's degree in pharmacy technology conferred by an institution accredited by one of the regional accrediting agencies recognized by the United States Department of Education; or
  (C) an associate's degree in pharmacy technology conferred by a program accredited by the American Society of Health System Pharmacists; and
(4) assists pharmacists with the preparation, dispensing and distribution of prescription medications that will be administered by a licensed health care provider to an inpatient in a Hospital under this Rule.

(f) Hospital. For the purposes of this Rule, a Hospital is either:

(1) a hospital licensed by the North Carolina Medical Care Commission; or
(2) a psychiatric hospital operated by the Secretary of the Department of Health and Human Services.

(g) Pursuant to G.S. 90-85.15A(c), the Board approves a pharmacist's supervision of more than two pharmacy technicians where the additional technicians are Validating Technicians. This Rule does not relieve the pharmacist-manager of the obligation to request and receive written Board approval for a pharmacist's supervision of more than two pharmacy technicians where the additional technicians are certified pharmacy technicians but are not Validating Technicians.
(h) A pharmacy technician performing validation functions described in this Rule as part of a Board-approved 21 NCAC 46 .2510 pilot project at Broughton State Hospital or Wake Forest University Baptist Medical Center may continue to perform such functions for a period of three years from this Rule's original effective date, after which time the pharmacy technician must meet all of the requirements specified in Paragraph (e) of this Rule to continue performing such functions.

History Note: *Authority G.S. 90-85.6; 90-85.15A; 90-85.21; 90-85.26; 90-85.32; 90-85.33; 90-85.34;*
Eff. June 18, 2011;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1419 AUTOMATED DISPENSING OR DRUG SUPPLY DEVICES

(a) Automated dispensing or drug supply devices may be used in health care facility pharmacies and where a pharmacy permit exists for a patient profile dispensing system, provided the utilization of the devices is under the supervision of a pharmacist. The pharmacist-manager shall develop and implement procedures to assure safe and effective use of medications and shall assure that:

(1) only authorized personnel, as indicated by written policies and procedures, may obtain access to the drug inventories;
(2) a system of accountability exists for all drugs contained therein and the purity, potency, and integrity of the drugs is preserved;
(3) requirements for controlled substances security are met; and
(4) prior to the drug being released for access by the nurse, the pharmacist enters the medication order into a computerized pharmacy profile that is interfaced to the automated dispensing unit, so that drug allergy screening, therapeutic duplication, and appropriate dose verification is done prior to the drug being administered.

(b) Notwithstanding the provisions of 21 NCAC 46 .2501, a pharmacist is required to supervise only the following activities pursuant to this Rule:

(1) The packaging and labeling of drugs to be placed in the dispensing devices. Such packaging and labeling shall conform to all requirements pertaining to containers and label contents;
(2) The placing of previously packaged and labeled drug units into the dispensing device; and
(3) The restocking of automated dispensing devices.

(c) Only persons authorized by the pharmacist-manager may remove drugs from the dispensing devices and only in the quantity of doses needed to satisfy immediate patient needs. Should a violation of the foregoing occur, the pharmacist-manager shall conduct an investigation and report any violations to the entity having jurisdiction over these issues.
(d) Bar code scanning of drug packaging and storage units may be utilized as a quality control mechanism if this technology is available in the automated dispensing system.
(e) An automated dispensing or drug supply device that is used solely as an Auxiliary Medication Inventory as defined in 21 NCAC 46 .1414(d) shall be governed by the requirements of that Rule.

History Note: *Authority G.S. 90-85.6; 90-85.32; 90-85.33;*
Eff. April 1, 1999;
Amended Eff. March 1, 2013; August 1, 2002;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017;
Recodified from 21 NCAC 46 .1814 Eff. May 1, 2021.

SECTION .1500 - ADMISSION REQUIREMENTS: EXAMINATIONS

21 NCAC 46 .1501 APPLICATION

(a) All applications for examination shall be made on forms provided by the Board, filed with the Board 45 days prior to the date of the examination, and accompanied by the required fee.
(b) All applicants shall submit to the Board a signed release form, completed Fingerprint Record Card, and such other form(s) required to perform a criminal history check at the time of application.

History Note: *Authority G.S. 90-85.6; 90-85.15; 90-85.24;*
Legislative Objection Lodged Eff. March 29, 1983;
Eff. April 1, 1983;
Curative Eff. April 1, 1983;
Amended Eff. July 1, 2005; May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1502 AGE

Proof of age must be shown by birth certificate, biblical records, or other acceptable proof.

History Note: *Authority G.S. 90-85.15; 93B-9;*
Eff. April 1, 1983;
Amended Eff. May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1503 EXPERIENCE IN PHARMACY AND PHARMACY INTERNSHIP

(a) An applicant for license must show that the applicant has received 1500 hours of practical experience under the supervision of a licensed pharmacist which has been acquired while enrolled in a school of pharmacy accredited by the Accreditation Council for Pharmacy Education.

(b) All practical pharmacy experience gained within the State of North Carolina must be acquired as follows:

(1) All practical pharmacy experience must be validated through registration in the internship program administered by the Board. A person does not receive credit for any practical experience unless and until that person is registered with the Board as a pharmacy intern.

(2) Practical experience shall be credited only when it has been obtained in a location holding a pharmacy permit, or a location approved by the Board for practical experience, and only after the pharmacy intern notifies the Board of the location of the practical experience. If the pharmacy intern's location of employment changes, the pharmacy intern must notify the Board of the change before commencing an internship at the new location.

(3) The person acquiring practical experience shall at all times comply with the Board's rules and the laws governing the practice of pharmacy and the distribution of drugs. Failure of the pharmacist intern to do so is grounds to disqualify the experience from counting toward the minimum requirements.

(4) The Board shall accept hours of experience certified by the school from which the applicant has graduated, provided that the applicant has satisfied Subparagraphs (1)-(3) of this Paragraph. The Board shall not allow credit for claims of practical experience required under the pharmacy laws, unless such claims can be corroborated by records on file in the Board's office showing the beginning and the ending of the practical experience claimed as supplied by the applicant during this training period.

(c) A person is eligible to register or renew and be employed as a pharmacy intern only if, and so long as, the person is:

(1) Currently enrolled in a pharmacy school accredited by the Accreditation Council for Pharmacy Education. In order to qualify as "enrolled" in a pharmacy school, the student must be attending pharmacy school at the time, or on a break between academic terms;

(2) A graduate of a foreign school of pharmacy who 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 and who is acquiring the practical experience required for licensure;

(3) A pharmacist licensed in another state who is gaining practical experience required for a license by reciprocity under Rule .1602 of this Chapter;

(4) A pharmacist with an inactive North Carolina license who is gaining practical experience required for reinstatement of a license under Rule .1612 of this Chapter;

(5) A graduate of a school of pharmacy who has not been licensed in any State, who has not been denied a license in any State, who has an active application for licensure to practice pharmacy in North Carolina and who has met all requirements for licensure other than taking and passing the North American Pharmacist Licensure Examination and the Multistate Pharmacy Jurisprudence Examination, and who is gaining practical experience to prepare for the examination in order to achieve licensure.

(d) In order to register or renew as a pharmacy intern, an applicant must submit proof of eligibility under Paragraph (c) of this Rule. The applicant further must provide releases for the Board to verify the applicant's eligibility, including confirming enrollment in or graduation from pharmacy school.

(e) Pharmacy intern registrations are valid until the September 1 immediately following registration. If the person remains eligible for registration as a pharmacy intern, the registration shall be renewed between August 1 and September 1 of the year in which the registration expires. If the registration expires for a pharmacy intern, that person is not eligible to work as a pharmacy intern in the State of North Carolina unless and until the registration is reinstated after a new application.
(f) If a pharmacy intern ceases to be eligible to be registered and employed as a pharmacy intern under Paragraph (c) of this Rule, that person must immediately cease working as a pharmacy intern and must notify the Board within five calendar days of a change in status and request that the person's registration be made inactive.
(g) The Board may accept practical experience gained in another state pursuant to internship registration in this or another state if the Board is satisfied that such experience is equivalent.
(h) A registered pharmacy intern working under a pharmacist preceptor or supervising pharmacist may, while under supervision of that pharmacist, perform all acts constituting the practice of pharmacy. Because the pharmacy intern may perform all acts constituting the practice of pharmacy under supervision under this provision, doing so without being registered with the Board is the unlicensed practice of pharmacy.
(i) A supervising pharmacist, pharmacist preceptor, or pharmacist-manager who causes or permits a pharmacy intern to violate any laws, rules, or regulations applicable to the practice of pharmacy or the distribution of drugs forfeits his or her right to supervise pharmacy interns and is subject to additional disciplinary action. A supervising pharmacist, pharmacist preceptor, or pharmacist-manager who violates any laws, rules, or regulations applicable to the supervision of pharmacy interns forfeits his or her right to supervise pharmacy interns and is subject to additional disciplinary action. This includes, but is not limited to, making false representations or withholding material information about the pharmacy intern's practical experience or employing a pharmacy intern who is not registered with the Board. A pharmacist who has been found in violation of laws, rules, or regulations governing the practice of pharmacy and the distribution of drugs cannot serve as a supervising pharmacist or pharmacist preceptor without the approval by the Board.
(j) The Board may consider any of the acts set forth in G.S. 90-85.38(a) that are committed by a pharmacy intern in considering whether to grant that person a license to practice pharmacy or what conditions are appropriate to ensure that the person can practice pharmacy safely.
(k) The practical experience hours gained prior to the effective date of any amendment to this Rule are governed by the requirements of this Rule in effect at the time the hours were obtained.

History Note: *Authority G.S. 90-85.6; 90-85.14; 90-85.15; 90-85.38;*
Eff. April 1, 1983;
Amended Eff. March 1, 2004; September 1, 1993; April 1, 1992; October 1, 1990; May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017;
Amended Eff. May 1, 2022.

21 NCAC 46 .1504 EDUCATION
All applicants shall furnish on forms provided by the Board satisfactory evidence that they have received an undergraduate professional degree from an approved school.

History Note: *Authority G.S. 90-85.15;*
Legislative Objection Lodged Eff. March 29, 1983;
Eff. April 1, 1983;
Curative Eff. April 1, 1983;
Amended Eff. May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1505 EXAMINATION
(a) The applicant shall pass the following examinations:
(1) the North American Pharmacist Licensure Examination ("NAPLEX"); and
(2) the North Carolina version of the Multistate Pharmacy Jurisprudence Examination ("MPJE").
(b) In order to pass either the NAPLEX or the MPJE, the applicant shall achieve the passing score set by the National Association of Boards of Pharmacy (or any organization designated by the National Association of Boards of Pharmacy to administer the NAPLEX or the MPJE).
(c) An applicant who achieves a passing score on one examination must achieve a passing score on the remaining examination within a two calendar year period starting from the date of the first passing score. Failure to achieve passing

scores on both examinations in this two calendar year period shall result in the applicant's application for licensure being denied. The applicant may, subject to the testing attempt limitations of Paragraph (d) of this Rule, reapply for licensure and restart the examination process.
(d) The applicant shall be afforded a total of five attempts to achieve a passing score on each examination. Failure to achieve a passing score on each examination within five attempts shall result in the applicant being ineligible for licensure.

History Note: *Authority G.S. 90-85.15; 90-85.16;*
Eff. April 1, 1983;
Amended Eff. May 1, 2017; April 1, 2004; April 1, 2003; July 1, 1996; December 31, 1985;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1506 RULES OF EXAMINATION CONDUCT

History Note: *Authority G.S. 90-85.6; 90-85.15; 90-85.16;*
Eff. April 1, 1983;
Amended Eff. May 1, 1989;
Expired Eff. November 1, 2017 pursuant to G.S. 150B-21.3A.

21 NCAC 46 .1507 PARTIAL EXAMINATION

History Note: *Authority G.S. 90-85.6; 90-85.15; 90.85.16;*
Eff. April 1, 1983;
Amended Eff. May 1, 1989;
Repealed Eff. January 1, 2009.

21 NCAC 46 .1508 PREREQUISITES FOR DISEASE STATE MANAGEMENT EXAMINATION

History Note: *Authority G.S. 90-85.6; 90-85.34;*
Eff. August 1, 2000;
Repealed Eff. July 1, 2005.

SECTION .1600 - LICENSES AND PERMITS

21 NCAC 46 .1601 PHARMACY PERMITS
(a) Applications for pharmacy permits, whether original or renewal, shall be made upon forms provided by the Board. The Board shall not issue any original or annual renewal pharmacy permit until the Board is satisfied that:

(1) The pharmacist-manager is sure that at all times adequate qualified personnel have been secured by the management of the store to properly render pharmaceutical service in the manner prescribed by law.
(2) The pharmacy posts in a location conspicuous to the public the specific hours that a pharmacist is on duty in the pharmacy. This requirement does not apply to hospitals, nursing homes, and similar institutions subject to the provisions of Section .1400 of this Chapter.
(3) The pharmacist-manager shall be responsible for obtaining and maintaining equipment in the pharmacy adequate to meet the pharmaceutical care needs of the pharmacy's patients.
(4) The pharmacist-manager shall be responsible for obtaining and maintaining a reference library in the pharmacy. The library shall include current references, either hard copy or electronically accessible, covering:
    (A) State and federal statutes and rules relating to the practice of pharmacy and the legal distribution of drugs;
    (B) Drug interactions, adverse effects, therapeutic use, dosing and toxicology;
    (C) Patient-oriented reference materials for counseling in proper drug usage as specified in 21 NCAC 46 .2504;
    (D) Equivalent drug products as defined in G.S. 90-85.27; and
    (E) Any reference materials otherwise required by state or federal law, including any otherwise required in these Rules.

(5) The pharmacy is equipped with sanitary appliances including lavatory facilities with hot and cold running water; is well lighted; and is kept in a clean, orderly, and sanitary condition.

(6) All prescription medications are labeled in accordance with G.S. 106-134 and 106-134.1.

(b) In addition to the requirements for issuance and renewal of a pharmacy permit imposed by statute and rules of the Board, a permit shall not be issued or renewed to any person to operate a pharmacy wherein the prescriptions of medical practitioners are compounded or dispensed and distributed when such distribution is effected by mail and the practitioner-pharmacist-patient relationship does not exist, until the Board is satisfied that:

(1) The pharmacy maintains records of prescriptions compounded or dispensed and distributed in manner that is readily retrievable;

(2) During the pharmacy's regular hours of operation but not less than six days per week, for a minimum of forty hours per week, a toll-free telephone service is provided to facilitate communication between patients and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number must be disclosed on the label affixed to each container of dispensed drugs;

(3) The pharmacy complies with all lawful orders, directions, and requests for information from the Boards of pharmacy of all states in which it is licensed and all states into which it distributes prescription drugs;

(4) The pharmacy complies with all United States Pharmacopeia and Food and Drug Administration requirements regarding the storage, packaging, and shipping of prescription medications. The pharmacist-manager and all other pharmacists employed in the pharmacies permitted pursuant to this Paragraph shall be subject to all Federal and State statutes and regulations concerning the dispensing of prescription medications including 21 NCAC 46 .1801 and .1805 and 21 CFR 1306.01, 1306.05, and 1306.21.

(c) The Board shall not issue an original or renewal permit to any person to operate a drugstore or pharmacy as a department in or a part of any other business serving the general public (except hospitals, nursing homes, and similar institutions subject to the provisions of Section .1400 of this Chapter) unless such pharmacy facility:

(1) is physically separated from such other business;

(2) is separately identified to the public both as to name and any advertising;

(3) completes all transactions relative to such pharmacy within the registered facility; and

(4) meets the same requirements for registration as all other pharmacies.

(d) In addition to all of the other requirements for issuance and renewal of a pharmacy permit imposed by statute and rules of the Board, the Board shall not issue any original or annual renewal pharmacy permit to any Internet pharmacy until the Board is satisfied that:

(1) The Internet pharmacy is certified by the National Association of Boards of Pharmacy under its Digital Pharmacy Accreditation program;

(2) The Internet pharmacy has certified the percentage of its annual business conducted via the Internet on a form provided by the Board, when it applies for permit or renewal; and

(3) The Internet pharmacy has provided the Board with the names, addresses, social security numbers, phone numbers, facsimile numbers, email addresses, and titles of all principal corporate officers of the Internet pharmacy; the names, addresses, social security numbers, phone numbers, facsimile numbers, email addresses, and titles of all principal officers of any company, partnership, association, or other business entity holding any ownership interest in the Internet pharmacy; the names, addresses, social security numbers, phone numbers, facsimile numbers, email addresses, and titles of any individual holding any ownership interest in the Internet pharmacy.

This Paragraph does not relieve an out-of-state pharmacy from compliance with all provisions of 21 NCAC 46 .1607 governing out-of-state pharmacies.

(e) Permits to operate pharmacies, whether original or renewal, shall be issued to the pharmacist-manager of such pharmacy pursuant to a joint application of the owner and pharmacist-manager for the conduct and management of said pharmacy. The issuance of said permit shall not be complete and the permit shall not be valid until it has been countersigned by the pharmacist-manager as represented in the application. The permit so issued is valid only so long as the pharmacist-manager to whom it was issued assumes the duties and responsibilities of pharmacist-manager. Permits may be reissued at any time to a successor pharmacist-manager pursuant to the proper amendment of the application for the permit.

(f) Upon application, the Board may issue and renew separate permits for pharmacies operating at one location. Records for each permitted pharmacy must be maintained separately. Prior to issuance of an original permit, each pharmacy shall submit a plan to the Board that shall assure accountability for the actions of each pharmacy at the location.

History Note: *Authority G.S. 90-85.6; 90-85.21; 132-1.10;*
Eff. April 1, 1983;

Amended Eff. November 1, 2012; April 1, 2007; April 1, 2003; April 1, 1999; October 29, 1998; July 1, 1996; September 1, 1995; May 1, 1989; August 1, 1988; March 1, 1984;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017; Amended Eff. May 1, 2020.

21 NCAC 46 .1602 LICENSE BY RECIPROCITY

(a) An applicant for licensure without examination, must have:

(1) Originally been licensed as a pharmacist by an examination equivalent to the North Carolina examination specified in Rule .1505(a)(1) of this Chapter;

(2) Achieved scores on an equivalent examination, such as the NABPLEX examination, which would qualify for licensure in this state at the time of examination; and

(3) Been licensed by a state which deems licensees from this state to be equivalent to the extent that they are suitable for licensure in that state without further substantial examination.

(b) All applicants shall submit to the Board a signed release form, completed Fingerprint Record Card, and such other form(s) required to perform a criminal history check at the time of application.

(c) The Board shall require an applicant for licensure without examination who has not practiced pharmacy within two years prior to application to obtain additional continuing education, practical pharmacy experience, successfully complete one or more parts of the Board's licensure examination, or a combination of the foregoing, as the Board deems necessary to ensure that the applicant can safely and properly practice pharmacy.

(d) The Board shall also restrict licenses granted pursuant to this Rule for such period of time as the Board deems necessary to ensure that the applicant can safely and properly practice pharmacy.

History Note: *Authority G.S. 90-85.6; 90-85.20;*
Eff. April 1, 1983;
Amended Eff. February 1, 2006; July 1, 2005; March 1, 2004; April 1, 2003, July 1, 1996; May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1603 WHEN NEW PERMIT REQUIRED

A new pharmacy, device, or medical equipment permit is required for a new location, a change to a different or successor business entity, or a change resulting in a different person or entity owning more than 50 percent interest in the permit holder or any entity in the chain of ownership above the permit holder, except as provided in 21 NCAC 46 .1604 of this Section. A new permit is required if there is a change in the authority to control or designate a majority of the members or board of directors of a nonprofit corporation holding a pharmacy permit or any nonprofit corporation in the chain of ownership above the permit holder.

History Note: *Authority G.S. 90-85.6; 90-85.21; 90-85.22;*
Eff. May 1, 1989;
Amended Eff. March 1, 2004; April 1, 2001; August 1, 1998; April 1, 1997; September 1, 1995;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1604 WHEN NEW PERMIT NOT REQUIRED

(a) A new pharmacy, device or medical equipment permit is not required in the following situations:

(1) the permit holder is a publicly-traded corporation and continues to hold the permit; or

(2) the permit holder is a corporation which is a wholly-owned subsidiary, and any change in the ownership of any corporation in the chain of ownership above the permit holder is due to the stock of such corporation being publicly-traded.

(b) A permit which has been served with a notice of hearing for a pending disciplinary proceeding before the Board may not be surrendered.

History Note: *Authority G.S. 90-85.6; 90-85.21; 90-85.22;*
Eff. May 1, 1989;
Amended Eff. June 1, 2004; April 1, 2001; August 1, 1998; May 1, 1997; September 1, 1995;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1605 CHARGE FOR VERIFICATION FOR REINSTATEMENT

History Note: *Authority G.S. 90-85.6; 90-85.17; 90-85.21; 90-85.22; 150B-19(5)(e);*
Eff. September 1, 1993;
Amended Eff. February 1. 2006; September 1, 1995;
Expired Eff. November 1, 2017 pursuant to G.S. 150B-21.3A.

21 NCAC 46 .1606 NORTH CAROLINA-SPECIFIC EDUCATION FOR PERMIT APPLICANTS

Prior to issuance of any original pharmacy permit or device and medical equipment permit, the pharmacist-manager for the applicant pharmacy or the person in charge of the facility applying for the device and medical equipment permit shall complete an educational module on the North Carolina Pharmacy Practice Act and the Board's regulations that govern the operation of permits. That educational module is available in the on-line permit application section of the Board's Licensure Gateway. The pharmacist-manager or person in charge must personally complete the educational module and may not delegate this responsibility to any other person.

History Note: *Authority G.S. 90-85.6; 90-85.21; 90-85.21A; 90-85.22;*
Eff. April 1, 1994;
Amended Eff. April 1, 2003; April 1, 1999; September 1, 1995;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017;
Amended Eff. May 1, 2022.

21 NCAC 46 .1607 OUT-OF-STATE PHARMACIES

(a) In order to protect the public health and safety and implement G.S. 90-85.21A, the following provisions apply to out-of-state pharmacies that ship, mail, or deliver in any manner a dispensed legend drug, device, or medical equipment into this State.

(b) An out-of-state pharmacy may not ship, mail, or deliver in any manner even a single dispensed legend drug, device, or piece of medical equipment into this State until it receives a permit from the Board. All unpermitted dispensing must be disclosed on any permit application, and any permit applicant must update any application within 24 hours of any dispensing into this State that occurs while a permit application is pending. The Board may deny a permit based on that dispensing or on a failure to disclose it.

(c) In addition to the requirements contained in G.S. 85-21A, these pharmacies shall:

(1) supply all information requested by the Board in carrying out the Board's responsibilities under the statutes and rules pertaining to out-of-state pharmacies;

(2) during the pharmacy's regular hours of operation but not less than six days per week, for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients and pharmacists at the pharmacy who have access to the patient's records. This toll-free number must be disclosed on the label for each dispensed drug, device, or piece of medical equipment;

(3) comply with all USP and FDA requirements regarding the storage, packaging, and shipping of drugs, devices, and medical equipment;

(4) develop policies governing:

(A) normal delivery protocols and times;

(B) the procedure to be followed if the patient's drug, device, or medical equipment is not available at the out-of-state pharmacy, or if delivery will be delayed beyond the normal delivery time;

(C) the procedure to be followed upon receipt of a prescription for a condition that requires treatment before the drug, device, or medical equipment would be delivered in the normal delivery time, which shall include a procedure for delivery of the drug, device, or medical equipment to the patient from the out-of-state pharmacy at the earliest possible time (such as courier delivery), or an alternative that assures the patient the opportunity to obtain the drug, device, or medical equipment at the earliest possible time; and

(D) the procedure to be followed when the out-of-state pharmacy is advised that the patient's drug, device, or medical equipment has not been received within the normal delivery time and that the patient is out of the drug, device, or medical equipment and requires interim dosage until the pharmacy can provide the drug, device, or medical equipment;

(5) disclose the location, names, and titles, of all officers and direct and indirect owners of the pharmacy. Disclose the names and license numbers of all pharmacists dispensing drugs, devices, or medical equipment to an ultimate user in this State, the names and, if available, license or registration numbers of all pharmacy personnel employed by the out-of-state pharmacy who assist pharmacists in dispensing. The pharmacist-

manager for the out-of-state permit issued by this Board must be the same person as the pharmacist-manager (whether called a pharmacist-manager, a person-in-charge or otherwise) of the pharmacy on the permit issued by the pharmacy's home state. A report containing this information shall be made on an annual basis and within 30 days of each change of any pharmacist-manager, officer, or owner (whether direct or indirect) of the pharmacy. A new permit shall be required under the circumstances set out in Rule .1603 of this Section, and a new permit must be secured before any legend drugs, devices, or medical equipment may be dispensed into the State of North Carolina following any of the enumerated changes in circumstances. The existing permit becomes void upon one of the events in Rule .1603, and any dispensing into the State of North Carolina following one of those events is unlawful and grounds for denial of a new permit;

(6) submit evidence of possession of a valid license, permit, or registration as a pharmacy in compliance with the laws of the state in which the pharmacy is located;

(7) designate a registered office and registered agent in North Carolina for service of process pursuant to Article 4 of Chapter 55D of the North Carolina General Statutes. The Board may serve or deliver any notice or other document provided for under the Pharmacy Practice Act or these Rules on that registered agent. The Board may further serve or deliver any notice or other document provided for under the Pharmacy Practice Act or these Rules on the Secretary of State when the Secretary of State becomes an agent of the entity pursuant to Article 4 of Chapter 55D of the North Carolina General Statutes; and

(8) notify the Board within five days of receipt of any order or decision by a Board of Pharmacy or other state or federal agency imposing discipline of any sort on the pharmacy, or receipt of any warning letter from the Food and Drug Administration.

(d) The facilities and records of an out-of-state pharmacy shall be subject to inspection by the Board. The Board also may require submission of inspection reports by the licensing entity of the state in which the pharmacy is located or records transmitted by the pharmacy to the Board offices.

(e) Any person who ships, mails, or delivers prescription drugs to North Carolina residents from more than one out-of-state pharmacy location shall register each pharmacy separately.

(f) An out-of-state permit holder may be disciplined as set forth in the Pharmacy Practice Act. The suspension or revocation of the pharmacy's home state permit will result in the immediate suspension or revocation of the out-of-state permit issued by this Board.

(g) An out-of-state pharmacy permit shall expire on December 31 of each year.

(h) The fees provided for in G.S. 90-85.21A as maximum fees which the Board is entitled to charge and collect are hereby established as the fees for each original permit and for annual renewal of each permit.

History Note: *Authority G.S. 90-85.6; 90-85.15A; 90-85.21A; 90-85.22; 90-85.26; 90-85.30; 90-85.32;*
Eff. July 1, 1994;
Amended Eff. March 1, 2006;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017;
Amended Eff. May 1, 2022.

21 NCAC 46 .1608 DEVICE AND MEDICAL EQUIPMENT PERMITS

(a) Applications for device and medical equipment permits, whether original or renewal, shall be made upon forms provided by the Board. The Board shall not issue any original or annual renewal device and medical equipment permit until the Board is satisfied that:

(1) Adequate qualified personnel have been secured by the management of the facility to properly render device and medical equipment services in the manner prescribed by law.

(2) Such personnel shall be maintained during the period for which the permit is issued.

(3) If the applicant dispenses medical oxygen to a patient, then the applicant must reasonably ensure that the following medical equipment is maintained:

(A) Sufficient backup of oxygen in that patient's home and supplies for equipment serviced to maintain continuation of therapy for 24 hours; and

(B) An oxygen analyzer in the permitted facility, if concentrators are dispensed.

(4) Suitable facilities shall be maintained to house inventory, to allow for fabrication work space, and to record and file prescription orders as required by law.

(5) A copy of the pharmacy laws of North Carolina, including the North Carolina Pharmacy Practice Act and the rules of the Board shall be present in the facility at all times.

(6) The facility is equipped with a functioning lavatory where hot and cold running water or hand washing appliances or waterless hand cleaner are available.
(7) The facility is kept in a clean, orderly, and sanitary condition.
(8) The applicants' services are accessible to its customer base.
(9) All prescription medications are labeled in accordance with G.S. 106-134 and 106-134.1.
(10) The applicant complies with all USP and FDA requirements regarding the storage, packaging, and shipping of prescription medications, including medical oxygen.
(11) The applicant's services are available 24 hours, seven days per week when essential to the maintenance of life or when the lack of such services might reasonably cause harm.
(12) The applicant implements and maintains a written procedure at each location for handling complaints and problems, which includes a complaint file documenting complaints and problems and resolution of the complaints or problems.
(13) The applicant complies with local/state fire and building laws.
(14) The applicant complies with current Occupational Safety and Health Administration (OSHA) laws and requirements as enforced by the NC Department of Labor/Division of OSHA, including the approach to infection control known as "Universal Precautions."

(b) Device and medical equipment permits, whether original or renewal, shall be issued to the person in charge of the facility pursuant to a joint application of the owner and person in charge. The issuance of said permit shall not be complete and the permit shall not be valid until it has been countersigned by the person in charge as represented in the application. The permit so issued is valid only so long as the person in charge to whom it was issued assumes his duties and responsibilities. Permits may be reissued at any time to a successor person in charge pursuant to the proper amendment of the application for the permit. The hours of operation shall be posted conspicuously at the facility for public viewing. The person in charge or the designee of the person in charge shall be present at the facility during the hours of operation of the facility. The person in charge shall notify the Board in writing of a change in the facility address within 30 days from the date of the change.

(c) When a device and medical equipment dispensing facility is to be closed permanently, the person in charge shall inform the Board of the closing and arrange for the proper disposition of devices and medical equipment and return the permit to the Board's offices within 10 days of the closing date. The person in charge, jointly with the owner (if the owner is someone other than the person in charge), shall provide for the orderly transfer of records to another permit holder for maintenance of patient therapy and inform the public of such transfer by posted notice or otherwise.

(d) Charitable organizations providing devices and medical equipment at no charge must register with the Board. The Board shall waive the fee for a permit upon a showing that the organization meets the Internal Revenue Service charitable purpose requirements for exemption from taxation and that at least 75 percent of the organization's funds are used for a charitable purpose. Loaner closets providing device and medical equipment at no charge, excluding oxygen or other life support devices, must register with the Board but are exempt from the fee for device and medical equipment permits.

History Note: *Authority G.S. 90-85.6; 90-85.22;*
Eff. September 1, 1995;
Amended Eff. April 1, 2007;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1609 PERMIT RENEWAL

Permits issued by the Board expire on December 31 and become invalid 60 days following expiration.

History Note: *Authority G.S. 90-85.6; 90-85.21;*
Eff. September 1, 1995;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1610 REINSTATEMENT OF FORFEITED LICENSING PRIVILEGES

An individual whose licensing privileges have been forfeited pursuant to G.S. 15A-1331, shall immediately surrender to the Board office his or her permit or license, current renewal certificate, and wallet card. In order to have the licensing privileges reinstated, the individual must appear before the Board and submit evidence that it would be in the public interest to reinstate the licensing privileges and that he or she can safely and properly practice pharmacy.

History Note: *Authority G.S. 15A-1331.1; 90-85.19;*
Eff. September 1, 1995;

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

21 NCAC 46 .1611 FEE FOR SUBMITTAL OF DISHONORED AND RETURNED CHECK

History Note: *Authority G.S. 25-3-506;*
Eff. September 1, 1995;
Amended Eff. February 1, 2006;
Expired Eff. November 1, 2017 pursuant to G.S. 150B-21.3A.

21 NCAC 46 .1612 REINSTATEMENT OF LICENSES AND PERMITS

(a) All licenses and registrations issued to individuals that are not renewed by March 1 of the succeeding year, lapse and are subject to the maximum reinstatement and renewal fees set out in G.S. 90-85.24 in order to be reinstated. All permits and registrations issued to locations that are reinstated after March 1 and prior to April 1 of the succeeding year are subject to the maximum reinstatement and renewal fees set out in G.S. 90-85.21A and 90-85.24. After March 31, permits and registrations issued to locations shall submit new applications and are subject to the maximum original registration fees. This Rule also applies to licenses, registrations, and permits reinstated following voluntary surrender or disciplinary action by the Board.

(b) All applicants shall submit to the Board a signed release form, completed Fingerprint Record Card, and such other form(s) required to perform a criminal history check at the time of application.

(c) The Board shall require applicants for reinstatement of a lapsed license who have not practiced pharmacy within two years prior to application for reinstatement to obtain continuing education in addition to that required by Rule .2201 of this Chapter, practical pharmacy experience, successfully complete one or more parts of the Board's licensure examination, or a combination of the foregoing, as the Board deems necessary to ensure that the applicant can safely and properly practice pharmacy.

(d) The Board shall also restrict licenses reinstated pursuant to G.S. 90-85.19 for such period of time as the Board deems necessary to ensure that the applicant can safely and properly practice pharmacy.

History Note: *Authority G.S. 90-85.19; 90-85.24;*
Eff. April 1, 1999;
Amended Eff. March 1, 2006; July 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1613 EXTENSION PERIOD FOR CERTAIN MEMBERS OF THE ARMED FORCES

(a) Definitions:

(1) "Eligible licensee" means a pharmacist who holds a license in good standing from the Board of Pharmacy, who serves the armed forces of the United States, and who is eligible for an extension of time in which to file a tax return pursuant to G.S. 105-249.2. "Eligible licensee" includes a pharmacist who holds a Clinical Pharmacist Practitioner credential or who is an immunizing pharmacist.

(2) "Eligible registrant" means a pharmacy intern, pharmacy technician, dispensing physician, dispensing optometrist, dispensing nurse practitioner or dispensing physician assistant who holds a registration in good standing from the Board of Pharmacy, who serves the armed forces of the United States, and who is eligible for an extension of time in which to file a tax return pursuant to G.S. 105-249.2.

(3) "Extension period" means the time period specified in 26 U.S.C. 7508.

(4) "Good standing" means a license or registration that is not suspended, revoked, or subject to a current disciplinary order.

(b) Extension of time to pay license or registration renewal fees and waiver of continuing education requirements:

(1) An eligible licensee or registrant shall notify the Board of eligibility for the extension period before his or her current license or registration expires. Upon such notification, the Board shall maintain the license or registration in active status through the extension period.

(2) If an eligible licensee or registrant fails to notify the Board of eligibility for the extension period before his or her current license or registration expires, upon receipt and acceptance of a renewal application within the extension period and presentation of proof that the licensee or registrant was an eligible licensee or registrant on the date that is the deadline for renewal, the expired license or registration shall be deemed retroactively to have not expired.

(3) Notwithstanding 21 NCAC 46 .1612(a) and .3301(a), an eligible licensee or registrant who submits a renewal application and pays the renewal fee required by the Board within the extension period shall not be deemed to hold a lapsed license or registration subject to reinstatement fees.

(4) Notwithstanding 21 NCAC 46 .2201, .3101(d) and .2507(c)(8), an eligible licensee may renew his or her license within the extension period despite failing to complete the specified continuing education requirements.

(5) A licensee or registrant shall provide proof of eligibility for the extension period when the licensee or registrant submits the renewal application.

History Note: *Authority G.S. 90-18.1; 90-18.2; 90-85.6; 90-85.15A; 90-85.15B; 90-85.17; 90-85.21(b); 90-85.24; 90-85.26A; 90-85.26B; 93B-15;*
Eff. April 1, 2010;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017;
Amended Eff. May 1, 2024; May 1, 2022.

21 NCAC 46 .1614 SUSPENSION OF AUTHORITY TO EXPEND FUNDS

In the event that the Board's authority to expend funds is suspended pursuant to G.S. 93B-2(d), the Board shall continue to issue and renew licenses, registrations and permits and collect all fees set forth in G.S. 90-85.24, but all fees tendered shall be placed in an escrow account maintained by the Board for this purpose. Once the Board's authority is restored, the funds shall be moved from the escrow account into the general operating account.

History Note: *Authority G.S. 90-85.6; 90-85.24;*
Eff. August 1, 2010;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1615 E-PROFILE NUMBER REQUIRED FOR LICENSE, PERMIT, OR REGISTRATION

(a) As part of the application for issuance or renewal of any in-state or out-of-state pharmacy permit, device and medical equipment permit, license to practice pharmacy, pharmacy intern registration, or pharmacy technician registration issued by the Board, the permittee, licensee, or registrant must report an e-Profile number to the Board.

(b) An applicant, permittee, licensee, or registrant may obtain an e-Profile number at no cost by contacting the National Association of Boards of Pharmacy by phone at (847) 391-4406; by mail at 1600 Feehanville Drive, Mount Prospect, Illinois 60056; or electronically at www.nabp.pharmacy.

History Note: *Authority G.S. 90-85.6; 90-85.14; 90-85.15; 90-85.15A; 90-85.17; 90-85.20; 90-85.21; 90-85.21A; 90-85.22;*
Eff. May 1, 2017;
Amended Eff. May 1, 2022.

21 NCAC 46 .1616 LIMITED SERVICE PERMITS

(a) The following pharmacy practice locations are eligible to apply for "limited service permits," which are pharmacy locations whose operations are modified by the provisions set forth in Paragraphs (b), (c), and (d) of 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) direct to patient systems that are not located at the home pharmacy's facility pursuant to Rule .1821 of this Chapter;

(4) facilities where drugs are dispensed only by nurse practitioners or physician assistants pursuant to Section .1700 of this Chapter;

(5) 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;

(6) 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;

(7) free clinics, as defined in G.S. 90-85.44(a)(6); or

(8) 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. The assistant pharmacist-manager shall be responsible for exercising all of the responsibilities of a pharmacist-manager when the assistant pharmacist-manager is present and the pharmacist-manager is not present at the location holding 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, if an assistant pharmacist-manager is desired at that time. If a designation is made or changed after the limited service permit application is filed, the pharmacist-manager shall notify the Board, 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), (2) and (3) of this Rule, either the pharmacist-manager or the assistant pharmacist-manager shall perform an in-person, on-site visit at least once per calendar quarter to inspect the location holding the permit, review the operations of the location holding the permit with the persons involved in accessing them as permitted by the rules referenced in Subparagraphs (a)(1), (2), and (3) of this Rule, and ensure that the location holding the permit is operated in compliance with all applicable State and federal laws.

(2) For limited service permits described in Subparagraphs (a)(4) and (5) of this Rule, either the pharmacist-manager or the assistant pharmacist-manager shall perform an in-person, on-site visit at least once per week to inspect the location holding the permit, review the operations of the location holding the permit with the persons involved in dispensing, and ensure that the location holding the permit is operated in compliance with all applicable State and federal laws.

(3) For limited service permits described in Subparagraphs (a)(6), (7) and (8) 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 shall 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 location holding the limited service permit may operate in the absence of a pharmacist only as set out in Rule .1413 of this Chapter.

(4) The limited service permit holder 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 shall accept the responsibilities of that position and shall be present as set forth in this Rule. A location holding 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 do so while also serving as the pharmacist-manager for a maximum of one permit other than a limited service permit. A person serving multiple limited service permit locations must fulfill all of that person's duties under State and federal law as to each location.

(e) Except as expressly set forth in this Rule, the pharmacist-manager must provide oversight and supervision as provided elsewhere in this Chapter.

History Note: *Authority G.S. 90-18.1(c); 90-18.2; 90-85.6; 90-85.21; 90-85.32; 90-85.33; 90-85.34;*
Eff. November 1, 2021;
Amended Eff. September 1, 2023.

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

21 NCAC 46 .1701 DISPENSING BY REGISTERED NURSE OR PHYSICIAN'S ASSISTANT
21 NCAC 46 .1702 DISPENSING SUPERVISED BY LICENSED PHARMACIST

History Note: *Authority G.S. 90-18.1; 90-18.2; 90-85.6;*
Eff. April 1, 1983;
Amended Eff. May 1, 1989;
Repealed Eff. April 1, 1997.

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) 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.
(d) The 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.
(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.

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;
Amended Eff. November 1, 2021.

21 NCAC 46 .1704 PREPACKAGING OF DRUGS DISPENSED
21 NCAC 46 .1705 RECORDS OF DISPENSING

History Note: *Authority G.S. 90-18.1; 90-18.2; 90-85.6; 90-85.36;*
Eff. April 1, 1983;
Amended Eff. September 1, 1995; May 1, 1989;
Repealed Eff. April 1, 1997.

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:

(1) 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;
(2) identify and resolve therapeutic duplication in each patient's medication regimen; and
(3) consider patient-specific medication contraindications.

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;
Amended Eff. November 1, 2021.

SECTION .1800 - PRESCRIPTIONS

21 NCAC 46 .1801 EXERCISE OF PROFESSIONAL JUDGMENT IN FILLING PRESCRIPTIONS

(a) A pharmacist or device and medical equipment dispenser shall have a right to refuse to fill or refill a prescription order if doing so would be contrary to his or her professional judgment.
(b) A pharmacist or device and medical equipment dispenser shall not fill or refill a prescription order if, in the exercise of professional judgment, there is or reasonably may be a question regarding the order's accuracy, validity, authenticity, or safety for the patient.

(c) A prescription order is valid only if it is a lawful order for a drug, device, or medical equipment issued by a health care provider for a legitimate medical purpose, in the context of a patient-prescriber relationship, and in the course of legitimate professional practice as recognized by the occupational licensing board governing the health care provider.

History Note: *Authority G.S. 90-85.6; 90-85.32;*
Eff. April 1, 1983;
Amended Eff. August 1, 2015; February 1, 2007; March 1, 2004; April 1, 2003; September 1, 1995;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1802 PRESCRIPTION REFILLS

(a) Authorization for prescription refills is presumed to be within the prescribed dosage or normal therapeutic use. Refilling prescriptions more frequently than the prescribed dosage would require, or refilling prescriptions in significant excess of normal therapeutic use, may be considered as negligence under G.S. 90-85.38(a)(9).

(b) If deemed appropriate in the pharmacist's professional judgment, a patient may receive upon request drug quantities in excess of the face amount of a prescription for a non-controlled substance, up to the total amount authorized. The pharmacist shall not dispense in excess of the face amount of a prescription for a controlled substance or psychotherapeutic drug without authorization from the prescriber.

History Note: *Authority G.S. 90-85.6; 90-85.32;*
Eff. April 1, 1983;
Amended Eff. September 1, 1993; May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1803 PRESCRIPTION RECORDS

All records pertaining to the filling and refilling of prescriptions shall be available to designated employees of the Board during normal business hours.

History Note: *Authority G.S. 90-85.6; 90-85.32; 90-85.36;*
Eff. April 1, 1983;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1804 PRESCRIPTION: RECEIVING AND DISPENSING

(a) In order to assure that the practitioner-pharmacist-patient relationship exists and to promote the safe and secure distribution of drugs and devices from a pharmacy, prescription orders may be received for filling and refilling only by a pharmacist or a bona fide employee of the pharmacy. The pharmacist-manager of the pharmacy shall be ultimately responsible for the safe, lawful and secure receipt of prescription orders and delivery of prescription drugs. Notwithstanding the provisions of this Rule, prescription drugs also may be delivered by mail in accordance with the provisions of 21 NCAC 46 .1601(b).

(b) In filling or refilling prescription orders, the pharmacist shall not be required to deal with parties, including managed care companies and insurance providers, outside the practitioner-pharmacist-patient relationship.

(c) In order to promote the safe and secure distribution of devices and medical equipment from a facility holding a device and medical equipment permit, prescription orders for devices and medical equipment may be received for filling and refilling only by the person in charge of the facility holding the device and medical equipment permit or a bona fide employee of the facility. The person in charge shall be ultimately responsible for the safe, lawful and secure receipt of prescription orders and delivery of devices and medical equipment. Unless the location also holds a pharmacy permit, a facility holding a device and medical equipment permit shall not acquire, receive, store, or deliver prescription drugs.

History Note: *Authority G.S. 90-85.6; 90-85.32;*
Eff. December 1, 1983;
Amended Eff. April 1, 2004; August 1, 2000; September 1, 1995; May 1, 1989; August 1, 1988;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1805 DISPENSING DRUGS WITHOUT A PRESCRIPTION

The dispensing of or any delivery of a prescription drug, including the surrender of control or possession in any manner which results in a delivery of a prescription drug, without a valid prescription order is unlawful. Refilling a prescription for a prescription drug without authorization is unlawful.

History Note: *Authority G.S. 90-85.3(s); 90-85.6; 90-85.32;*
Eff. March 1, 1984;
Amended Eff. May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1806 TRANSFER OF PRESCRIPTION INFORMATION

(a) The transfer of original prescription information for the purpose of refill dispensing is permissible between pharmacies subject to the following requirements:

(1) the transfer is communicated directly from either a pharmacist or certified technician to either a pharmacist or certified technician and not by only one pharmacist or certified technician gaining access to an information file containing data for several locations, unless all locations accessed are under common ownership or accessed pursuant to contractual agreement of the pharmacies;

(2) the transferring pharmacist or certified technician invalidates the prescription and any remaining refills at the transferring pharmacy by marking the word "void" on the face of the prescription or its equivalent;

(3) the transferring pharmacist or certified technician records the name and address of the pharmacy to which it was transferred and the name of the pharmacist or certified technician receiving the prescription information on the reverse of the invalidated prescription;

(4) the transferring pharmacist or certified technician records the date of the transfer and the name of the pharmacist or certified technician transferring the information.

(b) The pharmacist or certified technician receiving the transferred prescription information shall reduce to writing the following:

(1) The word "transfer" on the face of the transferred prescription;

(2) All information required to be on a prescription, including:

(A) Date of issuance of original prescription;

(B) Number of refills authorized on original prescription;

(C) Date and time of transfer;

(D) Number of valid refills remaining and date of last refill;

(E) Pharmacy's name, address and original prescription number from which the prescription information was transferred;

(F) Name of transferring pharmacist or certified technician; and

(G) Manufacturer or brand of drug dispensed.

(c) The transferred prescription, as well as the original, must be maintained for a period of three years from the date of last refill.

(d) Dispensing is permitted only within the original authorization for refills and no dispensing on such transfer shall occur beyond that authorized on the original prescription. Any dispensing beyond that originally authorized or one year, whichever is less, may occur only on a new prescription.

(e) The requirements of Paragraphs (a) and (b) of this Rule may be facilitated by use of a computer or data system without reference to an original prescription document. The system must be able to identify transferred prescriptions and prevent subsequent prescription refills at that pharmacy.

(f) This Rule applies to the transfer of prescriptions issued by prescribers in other states, provided that the pharmacist or certified technician receiving the prescription actually knows or reasonably should know that a physician-patient relationship exists and dispensing the drug is in the patient's best interests.

(g) All records pertinent to this Rule shall be readily retrievable.

(h) A system must be in place that will allow only authorized access by a pharmacist or certified technician to all records pertinent to this Rule and will indicate on the prescription record when and by whom such access was made.

(i) The transfer of original prescription information for the purpose of refill dispensing is permissible between device and medical equipment permit holders so long as the transferring permit holder provides all records and documentation necessary for dispensing and does not interfere with the service and claims processing procedures of the receiving permit holder.

History Note: *Authority G.S. 90-85.6(a); 90-85.32;*
Eff. December 31, 1985;

Amended Eff. June 1, 2004; September 1, 1995; July 1, 1992; May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1807 FACSIMILE TRANSMISSION OF PRESCRIPTION ORDERS

History Note: *Authority G.S. 90-85.6(a); 90-85.32;*
Eff. October 1, 1990;
Amended Eff. September 1, 1995;
Repealed Eff. March 1, 2004.

21 NCAC 46 .1808 REPACKAGED PHARMACEUTICALS

History Note: *Authority G.S. 90-85.6(a); 90-85.32;*
Eff. December 1, 1991;
Expired Eff. November 1, 2017 pursuant to G.S. 150B-21.3A.

21 NCAC 46 .1809 EMERGENCY PRESCRIPTION REFILLS

In the event a pharmacist or device and medical equipment permit holder receives a request for a prescription refill and the pharmacist or permit holder is unable to obtain refill authorization from the prescriber, the pharmacist or permit holder may dispense a one-time emergency refill of up to a 30 day supply of the prescribed medication, provided that:

(1) The prescription is not for a Schedule II controlled substance;
(2) The medication is essential to the maintenance of life or to the continuation of therapy in a chronic condition;
(3) In the pharmacist's or permit holder's professional judgment, the interruption of therapy might reasonably produce undesirable health consequences;
(4) The dispensing pharmacist or permit holder creates a written order containing all of the prescription information required by Section .2300 of these Rules and signs that order;
(5) The dispensing pharmacist or permit holder notifies the prescriber or the prescriber's office of the emergency dispensing within 72 hours after such dispensing.

History Note: *Authority G.S. 90-85.6; 90-85.25; 90-85.32;*
Eff. September 1, 1993;
Amended Eff. April 1, 1999; September 1, 1995;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1810 COMPOUNDING

History Note: *Authority G.S. 90-85.6; 90-85.32;*
Eff. September 1, 1995;
Amended Eff. August 1, 1998;
Repealed Eff. January 1, 2015.

21 NCAC 46 .1811 EXCESSIVE DISPENSING OF PRESCRIPTION DRUGS

Pharmacists shall not dispense and permit holders shall not allow a pharmacist to dispense prescription drugs at such a rate per hour or per day as to pose a danger to the public health or safety.

History Note: *Authority G.S. 90-85.6; 90-85.32;*
Eff. July 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1812 CHANGES IN PRESCRIPTION ORDERS

A permit holder or registrant requesting a change from the prescription drug originally prescribed to a different prescription drug shall disclose to the prescriber at the time of the request any business relationship between the permit holder or registrant and the manufacturer of the requested prescription drug.

History Note: *Authority G.S. 90-85.6; 90-85.32;*
Eff. April 1, 1997;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1813 TRANSMISSION OF PRESCRIPTION ORDERS

(a) Prescription orders may be transmitted by using a facsimile machine ("FAX") or by other electronic transmission from a prescriber to a pharmacy. "Electronic transmission" means transmission of the digital representation of information by way of electronic equipment.

(b) All prescription drug orders transmitted by FAX or by electronic transmission shall:

(1) be transmitted directly to a pharmacist or certified technician in a pharmacy of the patient's choice with no intervening person altering the content of the prescription drug order;

(2) identify the transmitter's phone number for verbal confirmation, the time and date of transmission, and the identity of the pharmacy intended to receive the transmission;

(3) be transmitted by an authorized practitioner or his designated agent and contain either a written signature or an electronic signature unique to the practitioner;

(4) be deemed the original prescription drug order, provided it meets all requirements of federal and state laws and regulations; and

(5) if a refill order, contain all information required for original prescription orders except for the prescriber's signature.

(c) The prescribing practitioner may authorize his agent to transmit by FAX or by electronic transmission a prescription drug order to a pharmacist or certified technician in a pharmacy provided that the identity of the transmitting agent is included in the order.

(d) The pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of a prescription drug order transmitted by FAX or by electronic transmission consistent with federal and state laws and regulations.

(e) All equipment for receipt of prescription drug orders by FAX or by electronic transmission shall be maintained so as to ensure against unauthorized access.

(f) Prescriptions may be transferred by FAX or by electronic transmission if all the requirements of Rule .1806 of this Section are met.

(g) No agreement between a prescriber and a pharmacy or device and medical equipment permit holder shall require that prescription orders be transmitted by FAX or by electronic transmission from the prescriber to only that pharmacy or device and medical equipment permit holder.

History Note: *Authority G.S. 90-85.6; 90-85.32;*
Eff. August 1, 1998;
Amended Eff. March 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1814 AUTOMATED DISPENSING OR DRUG SUPPLY DEVICES (RECODIFIED TO 21 NCAC 46 .1419 EFFECTIVE MAY 1, 2021)

21 NCAC 46 .1815 EMERGENCY PRESCRIPTION REFILL DUE TO INTERRUPTION OF MEDICAL SERVICES

In the event a pharmacist or device and medical equipment permit holder receives a request for a prescription refill and the pharmacist or permit holder is unable to readily obtain refill authorization from the prescriber because of the prescriber's inability to provide medical services to the patient, the pharmacist or permit holder may dispense a one-time emergency supply of up to 90 days of the prescribed medication, provided that:

(1) The prescription is not for a Schedule II controlled substance;

(2) The medication is essential to the maintenance of life or to the continuation of therapy in a chronic condition;

(3) In the pharmacist's or permit holder's professional judgment, the interruption of therapy might reasonably produce undesirable health consequences;

(4) The dispensing pharmacist or permit holder creates a written order entered in the pharmacy's automated data processing system containing all of the prescription information required by Section .2300 of these Rules and signs that order;

(5) The dispensing pharmacist or permit holder notifies, or makes a good faith attempt to notify, the prescriber or the prescriber's office of the emergency dispensing within 72 hours after such dispensing.

History Note: *Authority G.S. 90-85.6; 90-85.25; 90-85.32;*
Temporary Adoption Eff. October 29, 1998;
Eff. August 1, 2000;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1816 CENTRALIZED PHARMACY SERVICES

(a) This Rule sets out the requirements under which pharmacies may engage in "centralized pharmacy services," which consist of both centralized prescription filling services and remote medication order processing services, as defined in this Rule, with respect to any prescription to be dispensed by a pharmacy located within this State, or shipped, mailed, or delivered in any manner into this State.

(b) Regardless of whether located within or outside the State of North Carolina, the following requirements apply to any pharmacy involved with any part of the practice of pharmacy in centralized pharmacy services:

(1) The pharmacies must be permitted by the Board before providing any centralized pharmacy services.

(2) The pharmacies must either:

(A) Be owned by the same person or entity; or

(B) Before dispensing any prescription within or into this State, must have entered into a written contract that specifies the services to be provided and the responsibilities and accountabilities of each pharmacy to ensure compliance with state and federal statutes, rules, and regulations.

(3) The pharmacies must share a real-time, online database, or have technology to allow secure access to the pharmacies' information system and to provide access to the information required to provide centralized pharmacy services in compliance with state and federal statutes, rules, and regulations.

(4) The pharmacies, their pharmacist-managers, and their pharmacy personnel must comply with all provisions of the Pharmacy Practice Act, this Chapter and all other State of North Carolina and federal statutes, rules, and regulations applicable to the practice of pharmacy and the distribution of drugs, devices, and medical equipment, in addition to the statutes, rules, and regulations of the state(s) in which the pharmacies are located (if not located in North Carolina) and into which any drugs, devices, or medical equipment are shipped and dispensed (if not North Carolina). The pharmacies, their pharmacist-managers, and their pharmacy personnel are responsible for ensuring that these statutes, rules, and regulations are followed.

(5) The pharmacies must notify the Board before providing centralized pharmacy services.

(c) Centralized prescription filling services.

(1) "Centralized prescription filling services" consist of a receiving pharmacy receiving a prescription from an originating pharmacy, processing that prescription, and either:

(A) Delivering the drug, device, or medical equipment to the originating pharmacy for dispensing to the patient; or

(B) Delivering the drug, device, or medical equipment directly to the patient, if the patient requests delivery from the receiving pharmacy.

(2) In this Rule, the "originating pharmacy" is the pharmacy that was presented the prescription, whether by the patient or the prescriber or by transfer. In this Rule, the "receiving pharmacy" is the pharmacy that processes the prescription and delivers the drug, device, or medical equipment as set forth in Subparagraph (c)(1) of this Rule.

(3) The receiving pharmacy may process a request for the filling or refilling of a prescription order received by the originating pharmacy, provided:

(A) Both the originating pharmacy and the receiving pharmacy satisfy the requirements in Paragraph (b) of this Rule.

(B) The drug, device, or medical equipment is labeled with both the name and address of the receiving pharmacy and the name and address of the originating pharmacy; and

(C) The originating pharmacy satisfies all responsibility for compliance with the requirements of Federal and State statutes, rules, and regulations regarding recordkeeping and patient counseling, and the receiving pharmacy further maintains all required records of each prescription for at least three years.

(4) Centralized prescription filling services do not include prescriptions that are either:

(A) Transferred to another pharmacy to perform all acts related to dispensing or delivery, including recordkeeping and counseling, for which the pharmacies shall comply with the requirements for the originating pharmacy to transfer the prescription under Rule .1806 of this Chapter; or

(B) Prescriptions for which remote order processing services are performed, but all physical acts in the dispensing process are performed by the pharmacy to which the prescription was presented, for which the pharmacies shall comply with the requirements for remote medication order processing services in Paragraph (d) of this Rule.

(d) Remote medication order processing services.

(1) "Remote medication order processing services" consist of a pharmacy performing some act in the practice of pharmacy, other than a physical act in the dispensing process, for another pharmacy that dispenses a drug, device, or medical equipment. Remote medication order processing services include the following:

(A) receiving, interpreting, or clarifying medication orders;

(B) entering data and transferring medication order information;

(C) performing drug regimen review;

(D) interpreting patient clinical data to ensure proper prescription drug therapy;

(E) performing therapeutic interventions; and

(F) providing patient counseling or other drug information to patients and providers concerning prescriptions or drugs, devices, or medical equipment; however, if the drug, device or medical equipment is dispensed in person to the patient or the patient's agent, an offer must be made for a pharmacist at the dispensing pharmacy to counsel the patient in accordance with the requirements of Rule .2504 of this Chapter.

(2) In this Rule, the "dispensing pharmacy" is the pharmacy that was presented the prescription and dispenses the drug, device, or medical equipment. In this Rule, a "remote medication order processing pharmacy" is a pharmacy that provides an act in the practice of pharmacy for the dispensing pharmacy pursuant to this Rule.

(3) The remote medication order processing pharmacy may provide remote medication order processing services for the dispensing pharmacy, provided:

(A) The dispensing pharmacy and the remote medication order processing pharmacy satisfy the requirements in Paragraph (b) of this Rule.

(B) The pharmacies involved in remote medication order processing services jointly develop, maintain, and follow a manual of policies and procedures that include policies and procedures for:

(i) operation of the system described in Subparagraph (b)(3) of this Rule;

(ii) following the dispensing pharmacy's policies regarding medication order processing;

(iii) defining and ensuring the performance of each pharmacy's responsibilities;

(iv) maintaining contact information for how to communicate with the pharmacies at all times when remote medication order processing services are performed;

(v) training and annual review of pharmacy personnel of the remote medication order processing pharmacy;

(vi) communicating and resolving questions or problems arising during the remote medication order processing services;

(vii) communicating changes in the formulary to pharmacy personnel;

(viii) protecting the confidentiality and integrity of patient information;

(ix) identifying the name(s), initial(s) or identification code(s) and specific activity or activity of each pharmacy personnel who perform any remote medication order processing services;

(x) complying with all state and federal laws;

(xi) operating a quality improvement program designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, to pursue opportunities to improve patient care, and resolve identified problems;

(xii) updating these policies and procedures any time changes are necessary; and

(xiii) communicating changes in these policies and procedures to pharmacy personnel.

(C) The policy and procedures manual is reviewed at least annually, updated as needed, and any review and changes are documented and communicated to all pharmacy personnel.

(D) The remote medication order processing pharmacy trains all pharmacy personnel providing remote medication order processing services on the policies and procedures required by Part (B)

of this Subparagraph. The pharmacist-manager of the remote medication order processing pharmacy must ensure that pharmacy personnel are able to perform at the same level of competence, attention, and proficiency as if the personnel were in the dispensing pharmacy. The pharmacist-manager shall document all training.

(E) All remote medication order processing services are provided at a site operated by a remote medication order processing pharmacy, located within the United States, and with access to the technology required in Subparagraph (b)(3) of this Rule. This may include a remote site outside of the remote medication order processing pharmacy, so long as all requirements of state and federal statutes, rules, and regulations, including this Rule, are satisfied.

(F) Each remote medication order processing pharmacy must notify the Board of each pharmacist who will provide remote medication order processing services before those pharmacy personnel perform any such services.

(G) In order for the Board to ensure continual monitoring of pharmacist good standing, each pharmacist who will provide remote medication order processing services must either hold a North Carolina license to practice pharmacy or participate in the NABP Verify service before and at all times when that pharmacist provides remote medication order entry services. The remote medication order entry pharmacy must provide the NABP Verify information for each pharmacist when it notifies the Board that the pharmacist may provide remote medication order entry services.

(H) Pharmacy technicians may perform remote medication order processing services only if they are registered or otherwise permitted to work as a pharmacy technician in their home state. While pharmacy technicians either within or outside of this State may perform remote medication order processing services, pharmacy technicians may provide only those remote medication order processing services that both (a) they are permitted to perform under the laws of the state in which they are located, and (b) pharmacy technicians are permitted to perform under G.S. 90-85.3(q2), regardless of where they are located.

(I) The remote medication order processing pharmacy, its pharmacist-manager, and its pharmacy personnel are responsible for compliance with all state and federal statutes, rules and regulations and the pharmacies' policies and procedures governing the provision of remote medication order processing services.

(J) The dispensing pharmacy satisfies all responsibility for compliance with the requirements of state and federal statutes, rules, and regulations regarding recordkeeping, and the records document the activities of each pharmacy personnel providing remote medication order processing services and the specific activity or activities performed by each person. These records shall be maintained for a period of at least three years.

(4) Remote medication order processing services do not include services with respect to prescriptions in which some physical act in the dispensing process is performed by a pharmacy other than the dispensing pharmacy. If a pharmacy receiving a prescription from a patient or prescriber or by transfer wishes for another pharmacy to perform a physical act in the dispensing process, it must either transfer the prescription to that pharmacy under Rule .1806 of this Chapter, or follow the procedures for centralized prescription filling services in this Rule.

(e) Nothing in this Rule relieves a pharmacy receiving centralized pharmacy services (i.e., an originating pharmacy or a dispensing pharmacy) of the need to provide on-site services required for permitting as provided in the Pharmacy Practice Act and this Chapter.

History Note: *Authority G.S. 90-85.6; 90-85.21; 90-85.21A; 90-85.26; 90-85.32; 90-85.34;*
Eff. August 1, 2000;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017;
Amended Eff. March 1, 2022.

21 NCAC 46 .1817 PROOF OF IDENTIFICATION

(a) As a precondition to filling any prescription or dispensing any drug, a pharmacist or person acting at the direction of a pharmacist may demand, inspect and record proof of identification, including valid photographic identification, from any patient presenting a prescription or any person acting on behalf of the patient. Valid photographic identification includes but is not limited to the following:

(1) A valid motor vehicle operator's license;
(2) A valid identification card;
(3) A valid United States passport; or
(4) Other valid, tamper-resistant, photographic identification.

(b) A pharmacist or person acting at the direction of a pharmacist may exercise discretion and refuse to fill any prescription or dispense any drug if unsatisfied as to the legitimacy or appropriateness of any prescription presented, the validity of any photographic identification or the identity of any patient presenting a prescription or any person acting on behalf of the patient. Refusal to fill pursuant to this Paragraph shall be noted on the prescription by the pharmacist or person acting at the direction of a pharmacist.

History Notes: *Authority G.S. 90-85.6; 90-85.32;*
Eff. August 1, 2002;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1818 PRESCRIPTION LABELS

Prescription labels shall list at a minimum the generic name of the drug, even if the generic drug is unavailable to dispense or even if the substitution of a generic drug is not authorized.

History Note: *Authority G.S. 90-85.6; 90-85.32;*
Eff. January 1, 2006;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1819 COVID-19 DRUG PRESERVATION RULE

History Note: *Authority G.S. 90-85.6; 90-85.26; 90-85.32;*
Emergency Adoption Eff. April 1, 2020;
Temporary Adoption Eff. June 26, 2020;
Eff. February 1, 2021;
Repealed Eff. March 1, 2023.

21 NCAC 46 .1820 CODE OF ETHICS

All pharmacists must comply with the American Pharmacist Association Code of Ethics, which is hereby incorporated by reference, along with all subsequent amendments or editions. A copy of the Code of Ethics is available free of charge on the Board's website at http://ncbop.org/lawandrules.htm. Any contrary conduct is unprofessional conduct under G.S. 90-85.38.

History Note: *Authority G.S. 90-85.3A; 90-85.6; 90-85.15A; 90-85.15B; 90-85.22; 90-85.26; 90-85.26A; 90-85.32; 90-85.33; 90-85.34; 90-85.38; 90-85.44; S.L. 2021-110, s. 4.(a);*
Eff. July 1, 2022.

21 NCAC 46 .1821 DIRECT-TO-PATIENT DELIVERY SYSTEMS

(a) This Rule sets out the requirements under which pharmacies may utilize "direct-to-patient" or ("DTP") delivery systems for dispensing in the State of North Carolina.

(b) Definitions.

(1) "Direct to patient system" or "DTP system" means any delivery system through which a pharmacy dispenses drugs, devices or medical equipment to a patient through any means other than:
(A) in-person dispensing to a patient by pharmacy personnel inside a pharmacy,
(B) in-person dispensing by delivery to a patient's residence or to a health care provider treating that patient,
(C) shipping through common carrier to a patient or to a health care provider treating that patient, or
(D) the use of an automated dispensing device by a health care facility pharmacy that is governed by Rule .1419 of this Chapter.

Except as provided in this Rule or one of the exceptions set out in Parts (A)-(D) of this Subparagraph, no person holding any license or permit from the Board shall participate in any arrangement whereby prescriptions may be left at, picked up from, accepted by, or delivered to any other place. The only DTP systems allowed are "lockers" and "kiosks" as defined herein.

(2) The "home pharmacy" means the pharmacy responsible for dispensing drugs, devices or medical equipment through a DTP system.

(3) A "locker" means a secure container in which pharmacy personnel place labeled patient-specific drugs, devices, or medical equipment to be picked up by the patient.

(4) A "kiosk" means an automated system that is capable of filling, labeling, and dispensing drugs, devices, or medical equipment to be dispensed to a patient.

(c) Any DTP system located within the State of North Carolina (whether a locker or a kiosk) shall meet the following requirements:

(1) Before any drugs, devices, or medical equipment may be dispensed from a DTP system, the home pharmacy shall have been issued a pharmacy permit by the Board pursuant to G.S. 90-85.21 or 90-85.21A. In addition, before any drugs, devices, or medical equipment may be dispensed from the DTP system, the DTP system shall hold a limited service permit under Rule .1616 of this Section if it is not located at the home pharmacy's permitted facility.

(2) The home pharmacy shall notify the Board, in writing, through the home pharmacy's online permit portal, prior to beginning to use any DTP system, including the address and geographical coordinates of the DTP system and the licensed pharmacist(s) responsible for the DTP system. The home pharmacy shall notify the Board prior to moving the DTP system and shall secure a new limited service permit, if one is required by Subparagraph (c)(1) of this Rule, before operating the DTP system in the new location. The home pharmacy shall notify the Board within 10 days after discontinuing patient use of any DTP system.

(3) A DTP system shall be used exclusively by the home pharmacy.

(4) Any DTP system shall be 60 miles or fewer from the home pharmacy (via the shortest surface street route).

(5) A DTP system may be placed in the office of a prescriber only if the DTP system is under the control of the home pharmacy, which is responsible for compliance with all laws regarding the DTP system. The home pharmacy shall maintain the DTP system in the prescriber's office only if the prescriber offers patients a choice of pharmacy. The home pharmacy shall not give compensation to or receive compensation from the prescriber for the placement of the DTP system or for any prescriptions filled by the DTP system.

(6) The home pharmacy shall prohibit access to the DTP system and its contents by unauthorized personnel and maintain confidentiality of patient information. The DTP system shall be under the continuous supervision of a pharmacist employed by the home pharmacy, which may be satisfied by real-time remote supervision of the pharmacy through video and audio connections.

(7) The DTP system shall display the home pharmacy's name, address, phone number, North Carolina permit number, and the name of the home pharmacy's pharmacist-manager, as well as (where applicable) the limited service permit number for the DTP system and the name of the limited service permit's pharmacist-manager and assistant pharmacist-manager, if any.

(8) The home pharmacy shall ensure that there is continuous, recorded video surveillance of the DTP system and any persons using or accessing the DTP system. It shall maintain any recordings for a minimum of 90 days.

(9) The home pharmacy shall develop, maintain, and follow a manual of policies and procedures that includes policies and procedures for:

(A) Maintaining the security of the DTP system and the drugs, devices, and medical equipment within the DTP system.

(B) Determining and applying criteria regarding which drugs, devices, and medical equipment are appropriate for placement in the DTP system and which patients are eligible to use the DTP system.

(C) Maintaining any drugs, devices, and medical equipment at temperatures, humidities and other environmental conditions to ensure that they do not become adulterated under G.S. 106-133 and to ensure that they are transported and stored in accordance with manufacturer's specifications, if any, for those items.

(D) Removing outdated drugs, devices, and medical equipment from the DTP system as set forth in Subparagraph (c)(11) of this Rule on a regular basis so that patients do not receive drugs, devices, and medical equipment with a beyond use date during the period when the patient is to use the item.

(E) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filling procedures for the DTP system.

(F) Orienting participating patients on use of the DTP system; notifying patients when expected drugs, devices, or medical equipment are not available in the DTP system or when the DTP system is not functioning and notifying them of alternate methods for having those prescriptions filled; and ensuring that patient use of the DTP system does not interfere with the delivery of drugs, devices, and medical equipment to patients.

(G) Inspecting the DTP system during each required inspection.

This written manual of policies and procedures shall be reviewed and updated annually.

(10) The home pharmacy shall comply with any federal and state controlled substance laws and rules, including but not limited to registrations that may be required for any DTP systems, before any controlled substances are dispensed from any DTP systems. The home pharmacy shall comply with G.S. 90-106.1 in dispensing any drugs covered by that statute from a DTP system, and shall visually confirm that the person seeking the dispensation is the same as the person on the photographic identification provided.

(11) Only pharmacy personnel who are licensed with this Board as pharmacists or registered with this Board as technicians or pharmacy interns may stock drugs, devices, and medical equipment in, or remove drugs, devices, and medical equipment from, the inventory of a DTP system. The home pharmacy shall maintain records of any access to the DTP system by pharmacy personnel stocking or otherwise accessing the DTP system.

(12) Before a home pharmacy dispenses drugs, devices and medical equipment to a patient through a DTP system, the home pharmacy shall secure the affirmative consent of the patient to use the DTP system.

(13) The dispensing pharmacist on any drugs, devices, or medical equipment dispensed from a DTP system in the State of North Carolina shall be licensed with this Board.

(14) Before a prescription is dispensed from the DTP system, the dispensing pharmacist at the home pharmacy shall verify each prescription and shall conduct a drug utilization review and otherwise assure that the drug, device, or medical equipment may safely be dispensed to the patient.

(15) The labels of any drugs, devices, and medical equipment dispensed from a DTP system shall be labeled for the individual patient and contain all information required by law, including but not limited to having the dispensing pharmacist identified on the label.

(16) The home pharmacy shall create and maintain records of dispensing for any drugs, devices, and medical equipment dispensed in a DTP system in compliance with State and federal law. Any kiosk shall be connected to the home pharmacy's automated data processing system, and any drugs, devices, or medical equipment dispensed from any locker shall be recorded in the home pharmacy's recordkeeping system. The recordkeeping system shall be capable of producing a record of all drugs, devices, and medical equipment dispensed from the DTP system.

(17) The DTP system shall have a means to identify each patient (or that patient's authorized agent) and release only that patient's prescription drugs, devices, or medical equipment to the patient (or the patient's authorized agent).

(18) The DTP system shall convey the home pharmacy's offer to counsel a patient as required by Rule .2504 of this Chapter and shall provide the ability for the patient to have an immediate real-time consultation with a pharmacist licensed by this Board and employed by the home pharmacy who has access to all of the home pharmacy's information related to the patient. The communication link shall protect the confidentiality of the patient's information. The home pharmacy shall check the communication link at least daily and the DTP system shall be closed if the link malfunctions or if a licensed pharmacist is not available from the home pharmacy for counseling, unless a licensed pharmacist is physically present at the DTP system. A pharmacist who is responsible for counseling may not provide that service for more than three sites simultaneously. In the event that the DTP system is placed in the same physical space as the dispensing area of the home pharmacy, this provision may be satisfied during the time that the pharmacy is open by informing the patient how to receive counseling from a pharmacist in the home pharmacy. If the dispensing pharmacist has determined that the patient should receive counseling before the prescription is dispensed, the DTP system shall provide the ability for the pharmacist to force counseling before the DTP system dispenses the drug, device, or medical equipment.

(19) The home pharmacy shall record and review any incident involving a complaint, delivery error, or omission regarding a DTP as part of the home pharmacy's quality assurance program.

(20) Drugs, devices, or medical equipment that are not picked up by a patient may be returned to stock under the same conditions as if the item had been maintained in the pharmacy, as long as the requirements of this Rule for operating the DTP system have been followed.

(d) With respect to drugs, devices, or medical equipment dispensed through a kiosk, the following additional requirements shall be met:

(1) The dispensing pharmacist shall electronically compare via video link the stock bottle, drug dispensed, the strength, and the beyond-use date. The dispensing pharmacist shall verify the entire label for accuracy on the video link.

(2) The kiosk shall utilize a barcode system that prints the barcode of the stock bottle or other packaging on the label of the dispensed drug, device, or medical equipment. If the stock bottle or other packaging does not have a barcode, the home pharmacy shall create one. Pharmacy personnel shall scan both the stock bottle or other packaging and the label of the dispensed drug, device, or medical equipment to verify that the item dispensed is the same as the one in the stock bottle or other packaging for each prescription dispensed.

(3) Drugs, devices, or medical equipment dispensed by the kiosk shall be packaged only by a licensed manufacturer or repackager, or prepackaged by the home pharmacy in compliance with the Pharmacy Practice Act and this Chapter.

(4) The home pharmacy shall keep a perpetual inventory of controlled substances that are received and dispensed from each kiosk.

(5) The home pharmacy shall not dispense compounded medications through a kiosk.

(6) The kiosk shall not accept returns of drugs, devices and medical equipment from patients.

(e) This Rule does not alter the method by which patients or providers shall transmit prescriptions to the home pharmacy. Prescriptions may not be collected by the home pharmacy through the DTP system.

History Note: *Authority G.S. 90-85.6; 90-85.15A; 90-85.21; 90-85.32;*
Eff. September 1, 2023.

SECTION .1900 - FORMS

21 NCAC 46 .1901 DEFINITION

For use in the discharge of the statutory duties of the Board, it has adopted certain official forms which are described in this Section. Forms referred to in this Chapter are those forms described in this Section, and are available from the Board's office.

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

21 NCAC 46 .1902 APPLICATION FOR PHARMACIST'S LICENSE
21 NCAC 46 .1903 APPLICATION FOR PHARMACY PERMIT

History Note: *Authority G.S. 90-85.6; 90-85.15;*
Eff. April 1, 1983;
Amended Eff. May 1, 1989;
Expired Eff. November 1, 2017 pursuant to G.S. 150B-21.3A.

21 NCAC 46 .1904 RENEWAL OF PHARMACIST'S LICENSE

The form for application for renewal of a pharmacist's license is entitled "Pharmacist License Annual Renewal Notice," and must be completed and returned to the Board yearly for those individuals who desire to continue their license to practice pharmacy. This form requests updated information on the registrant's activity, nature of practice, and other matters.

History Note: *Authority G.S. 90-85.6; 90-85.17;*
Eff. April 1, 1983;
Amended Eff. May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1905 REPLACEMENT OF CERTIFICATES

The form for application for replacement of certificates is entitled "Order for Certificate of Registration." In addition to the ordinary identification information, this form requires the completion of an affidavit describing the loss or destruction of the original certificate.

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

21 NCAC 46 .1906 RECIPROCITY DATA QUESTIONNAIRE

The form for application to initiate reciprocity procedures is entitled "Reciprocity Data Questionnaire" and begins the process of reciprocating a pharmacist's license to North Carolina from another state. Along with the usual identification material, it requests information on education, experience, and other activities necessary to determine the person's eligibility to reciprocate.

History Note: *Authority G.S. 90-85.6; 90-85.20;*
Eff. April 1, 1983;
Amended Eff. May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1907 APPLICATION FOR RECIPROCITY

Following receipt from the applicant for reciprocity of the Data Questionnaire, the form for application for reciprocity, entitled "Preliminary Application for Reciprocal Licensure," will be mailed to the applicant by the Board to facilitate reciprocity through the National Association of Boards of Pharmacy. The form is printed by the National Association of Boards of Pharmacy and is distributed as a service to applicants by the North Carolina Board.

History Note: *Authority G.S. 90-85.6; 90-85.20;*
Eff. April 1, 1983;
Amended Eff. May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1908 REGISTRATION FOR PRACTICAL PHARMACY TRAINING

The form for registration for practical pharmacy training is entitled "Application for Registration in Pharmacy Training Program." This form must be completed by individuals at the beginning of the training necessary to be eligible for examination for licensure. Information requested includes identification, education, experience, supervising personnel, and location, along with approximate hours of training per week.

History Note: *Authority G.S. 90-85.6; 90-85.15;*
Eff. April 1, 1983;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1909 PRACTICAL PHARMACY EXPERIENCE

The form for certification of experience in North Carolina is entitled "Practical Pharmacy Experience Affidavit," and is used to certify training in North Carolina. This form requires information necessary to certify the hours completed and the preceptor responsible for training.

History Note: *Authority G.S. 90-85.6; 90-85.15;*
Eff. April 1, 1983;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .1910 CERTIFICATE OF EXPERIENCE OUTSIDE NORTH CAROLINA

History Note: *Authority G.S. 90-85.6; 90-85.15;*
Eff. April 1, 1983;
Amended Eff. May 1, 1989;
Repealed Eff. July 1, 1996.

21 NCAC 46 .1911 CERTIFICATE OF GRADUATION

History Note: *Authority G.S. 90-85.6; 90-85.15;*
Eff. April 1, 1983;
Amended Eff. May 1, 1989;
Expired Eff. November 1, 2017 pursuant to G.S. 150B-21.3A.

21 NCAC 46 .1912 APPLICATION FOR REGISTRATION AS A DISPENSING PHYSICIAN
21 NCAC 46 .1913 APPLICATION FOR DEVICE DISPENSING PERMIT

History Note: *Authority G.S. 90-85.6; 90-85.21; 90-85.22;*
Eff. February 1, 1991;
Expired Eff. November 1, 2017 pursuant to G.S. 150B-21.3A.

SECTION .2000 - ADMINISTRATIVE PROVISIONS

21 NCAC 46 .2001 FILING AND SERVICE

(a) Parties shall file all papers provided for in this Section with the Board, either before service or within five days after service. The Board shall consider a paper to be filed when the Board actually receives it. Parties shall direct filings to the Enforcement Manager, North Carolina Board of Pharmacy, 6015 Farrington Road, Suite 201, Chapel Hill, North Carolina 27517.

(b) In addition to filing all papers with the Board, the Board and other parties shall serve all papers as follows:

(1) The Board shall serve a notice of hearing under Rule .2006 of this Section on all parties by any method for service of process permitted by G.S. 150B-38(c).

(2) Parties shall serve subpoenas under Rule .2013 of this Section by any method for service permitted by G.S. 150B-39(c). While investigating, preparing for, or during a contested case, among others who are authorized to serve subpoenas, Board staff may serve subpoenas on behalf of the Board, pursuant to G.S. 1A-1, Rule 45.

(3) Parties shall serve all other papers in the contested case on all parties, including counsel to the Board, by any method for service permitted by G.S. 1A-1, Rule 5.

(4) The Board shall serve all its orders by any method for service permitted by G.S. 150B-42(a).

History Note: *Authority G.S. 90-85.6; 90-85.38; 150B-38; 150B-39; 150B-40; 150B-41; 150B-42;*
Eff. April 1, 1983;
Amended Eff. October 1, 1990; May 1, 1989; July 1, 1988; March 1, 1987;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017;
Amended Eff. March 1, 2024; August 1, 2020.

21 NCAC 46 .2002 RULES AND REGULATIONS SEVERABLE
21 NCAC 46 .2003 RULE-MAKING

History Note: *Authority G.S. 90-85.6; 150A-11; 150A-14;*
Eff. April 1, 1983;
Repealed Eff. May 1, 1989.

21 NCAC 46 .2004 REQUEST FOR HEARING

(a) A person aggrieved by a Board administrative action who has not received a notice of hearing from the Board may file a request for a hearing.

(b) The request for hearing shall contain the following information:

(1) the petitioner's name and address;

(2) a short and plain statement of the Board action that the petitioner challenges;

(3) a short and plain statement of the way in which the petitioner has been aggrieved; and

(4) an explicit statement of request for a hearing.

(c) In order to preserve a person's rights with respect to a Board action, the person shall file a request for hearing with the Board within 60 days after the person receives notice of the Board action that the person challenges.

History Note: *Authority G.S. 90-85.6; 150B-38;*
Eff. September 1, 1988;
Amended Eff. August 1, 2002;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017;
Amended Eff. August 1, 2020.

21 NCAC 46 .2005 GRANTING OR DENYING HEARING REQUEST

(a) The Board shall grant a request for a hearing if it determines that the petitioner is a "person aggrieved" within the meaning of G.S. 150B-2(6). The Board shall provide notice of the time and place for the hearing. If the party fails to appear, the Board may deny the party's request for failure to prosecute it or may proceed to hear the matter in the party's absence.
(b) If the Board determines the petitioner is not a person aggrieved, the Board shall issue a denial that shall constitute a final agency decision.

History Note: *Authority G.S. 90-85.6; 150B-38; 150B-40; 150B-42;*
Eff. July 1, 1988;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017;
Amended Eff. August 1, 2020.

21 NCAC 46 .2006 NOTICE OF HEARING

(a) Before imposing final discipline under G.S. 90-85.38 on a person who holds a license, registration, permit, or other privilege issued by the Board, the Board shall file and serve a notice of hearing pursuant to G.S. 150B-38(b).
(b) A party who has been served with a notice of hearing may file and mail to all other parties a written response not less than 10 days before the date set for the hearing. If the party wishes to submit this written response instead of personally appearing at the hearing, the party shall state that desire in the written response, and the Board shall consider the written response in lieu of a personal appearance.
(c) If a party who has been served with a notice of hearing neither appears pursuant to the notice nor files and serves a written response as set out in Paragraph (b) of this Rule, the Board shall rule the party to be in default and the allegations of the notice admitted. The Board may enter a final agency decision by default granting any relief available to the Board.
(d) If the Board determines that the public health, safety, or welfare requires action, it may summarily suspend a license, registration, permit, or other privilege granted by the Board. Upon service of the order, the licensee, registrant, or permit holder to whom the order is directed shall immediately stop practicing pharmacy and stop dispensing devices and medical equipment in North Carolina. Failure to receive the order shall not invalidate the order. The suspension shall remain in effect pending a final agency decision pursuant to G.S. 150B-42. However, pursuant to Rules .2004 and .2005 of this Section, a person subject to a summary suspension may request a hearing on whether the public health, safety, or welfare permits terminating or modifying the terms of the summary suspension pending a final agency decision. Neither an order of summary suspension nor a decision on whether the summary suspension order shall be terminated or modified is a final agency decision.

History Note: *Authority G.S. 90-85.6; 90-85.12; 90-85.38; 150B-3; 150B-38; 150B-40; 150B-42;*
Eff. July 1, 1988;
Amended Eff. September 1, 1995; May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017;
Amended Eff. August 1, 2020.

21 NCAC 46 .2007 WHO SHALL HEAR CONTESTED CASES

(a) A majority of the Board shall conduct all hearings, as set forth in G.S. 150B-40(b), except as provided in G.S. 150B-40(e).
(b) The Board President shall be the presiding officer at any hearing, unless the President is disqualified, absent, or otherwise determines that he or she is unable to serve in that capacity. In the event that the President does not preside, the Board Vice President shall be the presiding officer at any hearing, unless the Vice President is disqualified, absent, or otherwise determines that he or she is unable to serve in that capacity. In the event that neither the President nor the Vice President

preside, the Board shall designate another presiding officer. The presiding officer shall have all duties and powers set forth in G.S. 150B-40(c).

History Note: *Authority G.S. 90-85.6; 90-85.12; 150B-38; 150B-40;*
Eff. July 1, 1988;
Amended Eff. September 1, 1995;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017;
Amended Eff. August 1, 2020.

21 NCAC 46 .2008 INFORMAL PROCEDURES

(a) Before issuing a notice of hearing, the Board may conduct one or more conferences in which a member of the Board and the party or parties meet to consider the possibility of resolving the dispute or any other matter as may aid in the disposition of the dispute. The member of the Board may direct one or more of the following dispositions:

(1) Submission to the Board with a recommendation to dismiss with no action;
(2) Submission to the Board with a recommendation that Board staff provide informal guidance to resolve the dispute;
(3) Submission to the Board with a recommendation to resolve the dispute or to expedite the hearing by consent order; or
(4) Scheduling, with appropriate notice, for contested case hearing.

The Board must approve all recommendations under Subparagraphs (1), (2) and (3) of this Paragraph. The Board member who participated in the conference may participate in Board discussions concerning any recommendation made but may not vote upon the recommendation. The Board member who participated in the conference shall disqualify himself or herself in accordance with Rule .2011 of this Section from participation in any hearing or decision in the matter discussed in the conference if the matter results in a contested case hearing before the Board.

(b) The Board and the party or parties may agree to simplify the hearing by stipulation or any other method provided by G.S. 150B-41(c).

History Note: *Authority G.S. 90-85.6; 150B-38; 150B-39; 150B-40; 150B-41; 150B-42;*
Eff. July 1, 1988;
Amended Eff. April 1, 2001; September 1, 1995; October 1, 1990; May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017;
Amended Eff. August 1, 2020.

21 NCAC 46 .2009 MOTIONS

Except as otherwise provided in this Section, parties must file and serve motions related to a contested case at least ten days before the hearing, except those made during the hearing. The presiding officer may decide to hear pre-hearing motions either before the hearing or at the hearing before witnesses testify.

History Note: *Authority G.S. 90-85.6; 150B-38; 150B-39; 150B-40; 150B-41;*
Eff. July 1, 1988;
Amended Eff. May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017;
Amended Eff. August 1, 2020.

21 NCAC 46 .2010 TYPES OF INTERVENTION

History Note: *Authority G.S. 90-85.6; 150B-38;*
Eff. July 1, 1988;
Amended Eff. May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017;
Repealed Eff. August 1, 2020.

21 NCAC 46 .2011 DISQUALIFICATION OF BOARD MEMBERS

(a) If a Board member determines that personal bias or other reason for that Board member's disqualification exists in a contested case, that Board member shall decline to participate in the hearing or decision.

(b) If any party in a contested case, in good faith, has evidence that a Board member is personally biased or another reason for disqualification exists, the party may file and serve a motion for disqualification, which must be supported by a sworn, notarized affidavit testifying to the facts relevant to disqualification.
(c) Ex parte communication by or on behalf of a party with a Board member about the facts of a case at any time during either the investigation or prosecution of potential violations shall be grounds for disqualification of that Board member, other than communications by Board counsel and staff during the course of seeking a summary suspension or communications during any other proceeding before the Board. Before a hearing begins, or during the hearing, if applicable, both the Board member and the party must disclose the communications between the Board member and a party about the facts of the case to the Board and to the parties.
(d) A party may file and serve a motion for disqualification less than ten days before or during a hearing only when based on newly discovered evidence that by due diligence could not have been discovered in time to file a timely motion. Under these circumstances, the hearing shall continue with the challenged Board member sitting.
(e) The Board shall decide whether the evidence requires disqualification before it renders the final agency decision in the contested case. The decision about the disqualification of a Board member shall be made by the other Board members. The Board is not required to grant a new hearing if a Board member is disqualified during the course of a hearing.
(f) The presiding officer may determine the method of resolving the motion for disqualification in the presiding officer's discretion under G.S. 150B-40. This may include the authority to direct that the Board's Executive Director oversee an investigation of the allegations and report the findings to the Board.
(g) In the event of disqualification, the disqualified member shall not participate in further deliberation or decision of the case but may be called on to furnish information to the other members of the Board.
(h) If three or more members of the Board are disqualified pursuant to this Rule, the Board shall petition the Office of Administrative Hearings to appoint an administrative law judge to hear the contested case pursuant to G.S. 150B-40(e).

History Note: *Authority G.S. 90-85.6; 150B-38; 150B-39; 150B-40; 150B-41;*
Eff. July 1, 1988;
Amended Eff. May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017;
Amended Eff. August 1, 2020.

21 NCAC 46 .2012 RESERVED FOR FUTURE CODIFICATION

21 NCAC 46 .2013 SUBPOENAS
(a) A party shall file and serve a request for a subpoena, attaching a proposed subpoena. A form of subpoena is available on the Board's website at ncbop.org/lawandrules.htm. The Board may issue the subpoena in accordance with G.S. 150B-39(c). Subpoenas must be issued and signed by the Presiding Officer, the Board's Executive Director, the Board's legal counsel, or a Board staff member designated by the Executive Director.
(b) The party shall serve the subpoena along with the fees and expenses required by G.S. 150B-39(c).
(c) After service of the subpoena, the party serving the subpoena shall file and serve sworn proof of the method of service, demonstrating compliance with G.S. 150B-39(c).
(d) G.S. 150B-39(c) governs the recipients' duties in responding to subpoenas. A party to the case or person subject to the subpoena may object to a subpoena by filing a motion to quash. The movant shall file and serve the motion to quash within 10 days of service of the subpoena or seven days before the contested case hearing, whichever is sooner. The Board shall hear and rule on objections as provided in G.S. 150B-39(c).

History Note: *Authority G.S. 90-85.6; 150B-38; 150B-39; 150B-40;*
Eff. September 1, 1988;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017;
Amended Eff. August 1, 2020.

21 NCAC 46 .2014 WITNESSES
All testimony at the hearing shall be under oath or affirmation and shall be recorded. The presiding officer may exclude witnesses from the hearing room so that they cannot hear the testimony of other witnesses.

History Note: *Authority G.S. 90-85.6; 150B-38; 150B-39; 150B-40; 150B-41; 150B-42;*
Eff. July 1, 1988;

Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017; Amended Eff. August 1, 2020.

21 NCAC 46 .2015 FINAL DECISION

In a contested case, the Board shall issue a final agency decision in compliance with G.S. 150B-42. All final agency decisions shall be drafted by Board staff or Board counsel and presented to the presiding officer. In the event that the presiding officer determines that the drafted order does not reflect the Board's findings of fact, conclusions of law, or ruling, the presiding officer shall revise the drafted order to reflect the Board's decision.

History Note: *Authority G.S. 90-85.6; 90-85.38; 150B-3; 150B-38; 150B-40; 150B-41; 150B-42;*
Eff. July 1, 1988;
Amended Eff. May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017;
Amended Eff. August 1, 2020.

21 NCAC 46 .2016 PROPOSALS FOR DECISIONS

(a) When an administrative law judge conducts a hearing pursuant to G.S. 150B-40(e), that statute governs the procedures before the administrative law judge.

(b) Within 10 days after the proposal for decision is served on the parties under G.S. 150B-40(e), a party may file and serve written exceptions to this proposal for decision and submit its own proposed findings of fact and conclusions of law. The party shall explicitly state what exceptions are taken to the decision or procedure and what relief the party seeks. Exceptions must refer to pages of the record or otherwise identify the occurrence to which the party takes exception. Each proposed finding of fact shall refer to pages of the record or otherwise identify the evidence supporting the proposed finding, and each proposed conclusion of law must refer to or otherwise identify both the findings of fact and legal support for the proposed conclusion. A party may file and serve written arguments along with the exceptions and proposed findings of fact and conclusions of law.

(c) A party may ask to present oral argument to the Board. The party must file and serve the request with the written submissions under Paragraph (b) of this Rule. If a party requests oral argument, the Board will notice the time and place for such oral argument. The presiding officer may set the terms of oral argument, including order of argument and time limitations.

(d) After the procedures set forth in this Section, the Board will issue a final agency decision in accordance with Rule .2015 of this Section.

History Note: *Authority G.S. 90-85.6; 150B-38; 150B-40; 150B-41; 150B-42;*
Eff. July 1, 1988;
Amended Eff. May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017;
Amended Eff. August 1, 2020.

21 NCAC 46 .2017 REAPPLICATIONS, REINSTATEMENT, REHEARING, AND RECONSIDERATION

(a) The following terms govern reapplication, reinstatement, rehearing, and other reconsideration requests from a final agency decision, unless otherwise expressly provided in that final agency decision:

(1) No individual who holds a license, registration, or other privilege from the Board who has that license, registration, or other privilege either revoked or actively suspended indefinitely or for more than five years may petition for reinstatement, to have the revocation or suspended lifted, for reconsideration or rehearing, or otherwise for modification or rescinding the order, until at least five years from the effective date of the revocation or suspension.

(2) No individual who has had an application for a license, registration, or other privilege from the Board denied may submit another application or petition for reconsideration or rehearing or otherwise for modification or rescinding the denial, until at least two years from the date of the most recent application that the Board denied. At that time, the individual must submit a new application for the Board to consider.

(3) No permit holder who has had that permit either revoked or actively suspended indefinitely or for more than five years may submit another application or petition for reinstatement, to have the revocation or suspended lifted, for reconsideration or rehearing, or otherwise for modification or rescinding the order, until at least five years from the effective date of the revocation or suspension.

(4) No proposed permit holder who has had an application for a permit denied may submit another application for a permit or petition for reconsideration or rehearing or otherwise for modification or rescinding the denial, until at least two years from the date of the most recent application that was denied. At that time, the proposed permit holder must submit a new application for the Board to consider.

(5) If any license, registration, permit, or any other privilege is subject to a stayed suspension or an active suspension for a period of five years or shorter, the person holding that privilege may not submit another application, or petition for reinstatement, to have the suspension lifted, for reconsideration or rehearing, or otherwise for modification or rescinding the order, before the conclusion of that suspension.

(6) For the purposes of Subparagraphs (3), (4), and (5) of this Paragraph, the Board shall treat a permit holder or proposed permit holder the same as a prior permit holder or proposed permit holder if either of the following two conditions is true:

(A) the permit holder or proposed permit holder has the same pharmacy manager and there is more than 10 percent common ownership as the prior permit holder or proposed permit holder; or

(B) the permit holder or proposed permit holder has 50 percent or more common ownership as the prior permit holder or proposed permit holder.

To determine common ownership under this Rule, the Board shall consider business entities to be identical to other business entities if there is more than a 50 percent common ownership. Furthermore, to determine common ownership under this Rule, the Board shall combine the interests of individuals with the interests of any business entities in which the individuals have more than a 10 percent interest, as well as with the interests of individuals in the same family.

(b) The Board may alter the terms provided in Paragraph (a) of this Rule, after applying the facts and circumstances of the matter and its application of the disciplinary provision in G.S. 90-85.38. Unless the Board expressly modifies these terms in the final agency decision, the terms of Paragraph (a) of this Rule apply to that decision.

(c) If a person submits a petition or application that does not meet the requirements set forth in this Rule, the Executive Director shall not schedule any hearing on the petition or application before the Board until the limits set forth in this Rule are satisfied.

(d) Upon a petition for reinstatement or to submit a new application permitted under this Rule, the Board will grant or reinstate a license, registration, permit, or other privilege only after a finding that the grant or reinstatement is appropriate under the Pharmacy Practice Act and the Board's rules and regulations. In making that decision, the Board will consider the gravity of the misconduct that caused the denial, suspension, or revocation; the applicant's history; the applicant's current ability to practice pharmacy with reasonable skill, competence, and safety to the public; and the applicant's conduct since the order of denial, suspension, or revocation.

History Note: *Authority G.S. 90-85.6; 90-85.38; 150B-38; 150B-40; 150B-42;*
Eff. August 1, 2020.

SECTION .2100 - ELECTIONS

21 NCAC 46 .2101 BOARD OF PHARMACY ELECTIONS: COMPOSITION AND DUTIES

History Note: *Authority G.S. 90-85.7;*
Eff. April 1, 1983;
Repealed Eff. May 1, 1989.

21 NCAC 46 .2102 ELIGIBILITY TO VOTE

Eligible voters for Board members shall be the pharmacists licensed in North Carolina and residing in North Carolina on October 31 of the year the election begins.

History Note: *Authority G.S. 90-85.7; 90-85.22;*
Eff. April 1, 1983;
Amended Eff. May 1, 2017; September 1, 1995; May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017;
Amended Eff. April 1, 2020.

21 NCAC 46 .2103 GEOGRAPHIC REPRESENTATIONS

Pharmacist members of the Board shall be elected from five geographic areas of the state. These five geographic areas are:

(1) The Western District, consisting of Alexander, Alleghany, Ashe, Avery, Buncombe, Burke, Caldwell, Catawba, Cherokee, Clay, Cleveland, Gaston, Graham, Haywood, Henderson, Jackson, Lincoln, Macon, Madison, McDowell, Mitchell, Polk, Rutherford, Swain, Transylvania, Watauga, Wilkes and Yancey Counties;

(2) The Northern District, consisting of Alamance, Caswell, Forsyth, Guilford, Orange, Person, Rockingham, Stokes, Surry and Yadkin Counties;

(3) The Central District, consisting of Anson, Cabarrus, Chatham, Davidson, Davie, Iredell, Lee, Mecklenburg, Montgomery, Moore, Randolph, Richmond, Rowan, Stanly and Union Counties;

(4) The Northeastern District, consisting of Bertie, Camden, Chowan, Currituck, Dare, Durham, Edgecombe, Franklin, Gates, Granville, Halifax, Hertford, Hyde, Martin, Nash, Northampton, Pasquotank, Perquimans, Tyrell, Vance, Wake, Warren, Washington and Wilson Counties; and

(5) The Southeastern District, consisting of Beaufort, Bladen, Brunswick, Carteret, Columbus, Craven, Cumberland, Duplin, Greene, Harnett, Hoke, Johnston, Jones, Lenoir, New Hanover, Onslow, Pamlico, Pender, Pitt, Robeson, Sampson, Scotland and Wayne Counties.

History Note: *Authority G.S. 90-85.7;*
Eff. April 1, 1983;
Amended Eff. May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2104 COMMITTEE ON NOMINATIONS

In the event that no eligible candidates have petitioned for nomination, the Board may appoint an advisory committee on nominations in September of each year that an election for Board position(s) begins. Members of this committee shall submit at least two names of eligible candidates for each position to be filled on the Board by October 1 for the next election.

History Note: *Authority G.S. 90-85.7;*
Eff. April 1, 1983;
Amended Eff. May 1, 2017; July 1, 1996; May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017;
Amended Eff. April 1, 2020.

21 NCAC 46 .2105 NOMINATION BY PETITION

Nominations may also be made by the petition of 10 eligible voters from a geographic area as specified in Rule .2103 of this Section. Any petition shall be filed in the Board office or postmarked before October 1 for the next election.

History Note: *Authority G.S. 90-85.7;*
Legislative Objection Lodged Eff. March 29, 1983;
Eff. April 1, 1983;
Curative Eff. April 1, 1983;
Amended Eff. May 1, 2017; May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2106 CONSENT TO NOMINATION

A person's name shall not be placed on the ballot without their written consent.

History Note: *Authority G.S. 90-85.7;*
Eff. April 1, 1983;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2107 BALLOTS: CASTING AND COUNTING

(a) The ballot casting period for each election for a Board position shall begin on the November 1 six months prior to the expiration of a Board member's five-year term of office and shall conclude the March 1 after the ballot casting period begins.

(b) The Board shall provide access to an electronic ballot to all eligible voters on November 1 of each year that an election for Board position(s) begins.
(c) A description of a nominee's qualifications shall be accessible to all eligible voters.
(d) On or before the March 1 that the ballot casting period ends, all ballots shall be cast electronically.
(e) Ballots received shall be counted and certified by the Board of Pharmacy at the next regularly scheduled Board meeting following an election or at a special Board meeting called and noticed for the purpose of counting and certifying the ballots cast. The Board of Pharmacy shall determine the validity of any challenged ballot, and electronic or mechanical devices may be used in compiling election results. No person standing for election may participate in the counting and certification of ballots for the election involving that person.
(f) If, by operation of Rule .2108 of this Section, a candidate is eligible to request a run-off election, that candidate must provide a request for a run-off, in writing to the Board's Executive Director within one week of the date that the Board certifies the election results. The run-off election shall begin one week from the date that the eligible candidate requests the run-off election and the ballot casting period shall be open for two weeks. With the exception of ballot casting period dates, a run-off election shall follow the same procedures described in this Rule.
(g) The Executive Director shall convey the certified election results to the Governor.

History Note: *Authority G.S. 90-85.7;*
Eff. April 1, 1983;
Amended Eff. May 1, 2017; January 1, 2009; April 1, 2003;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2108 DETERMINATION OF ELECTION RESULTS

The determination of election results under this Section shall be in accordance with G.S. 163-111(a)(1) and (b)(1). A copy of G.S. 163-111 is available at www.ncleg.net.

History Note: *Authority G.S. 90-85.7;*
Eff. March 1, 1991;
Amended Eff. May 1, 2017; December 1, 2001;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2109 DEVICE AND MEDICAL EQUIPMENT COMMITTEE REPRESENTATIVES

History Note: *Authority G.S. 90-85.6; 90-85.22;*
Eff. September 1, 1995;
Amended Eff. April 1, 2003;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017;
Repealed Eff. April 1, 2020.

SECTION .2200 - CONTINUING EDUCATION

21 NCAC 46 .2201 HOURS: RECORDS: PROVIDERS: CORRESPONDENCE: RECIPROCITY

(a) As a condition of license renewal, a pharmacist shall accumulate 15 hours of continuing education annually.
(b) Five of these continuing education hours shall be obtained through contact programs. Contact programs are those in which there is an opportunity for live two-way communication between the presenter and attendee. An online continuing education course may satisfy this contact-hour requirement provided that the continuing education course includes live two-way communication between the presenter and attendee.
(c) A pharmacist shall preserve all continuing education records for three years. If a continuing education provider approved in Paragraph (e) of this Rule maintains an electronic database of all pharmacists granted continuing education credits accredited by the provider, then the storage of that information in the provider's database shall be deemed to satisfy the pharmacist's recordkeeping requirement.
(d) Upon license renewal, the pharmacist shall report continuing education hours through the Board's online license renewal portal. The Board may require a pharmacist to submit records, reports of accredited hours and certificates of credit on a random basis pursuant to a continuing education audit.
(e) All continuing education shall be obtained through continuing education courses accredited by the Accreditation Council for Pharmacy Education or the North Carolina Association of Pharmacists. Pharmacists may also acquire five hours

continuing education credit for precepting, for at least 160 hours, a student enrolled in the University of North Carolina Eshelman School of Pharmacy, the Campbell University College of Pharmacy and Health Sciences, the Wingate University School of Pharmacy, or the High Point University Fred Wilson School of Pharmacy as part of these schools' academic program.

(f) A pharmacist shall be exempt from the requirements of this Rule if:

(1) The pharmacist is eligible for a waiver of continuing education requirements under 21 NCAC 46 .1613; or

(2) For the entire year preceding license renewal, the pharmacist resided in another state, did not practice pharmacy in North Carolina, and satisfied the state of residence's continuing education requirements for pharmacist licensure.

(g) Continuing education shall not serve as a barrier to reciprocity; however, all licensees by reciprocity must observe the continuing education standards specified in Paragraphs (a), (b), (c), (d), (e) and (f) of this Rule within the first renewal period after licensure in this state.

History Note: *Authority G.S. 90-85.6; 90-85.17; 90-85.18;*
Eff. January 1, 1985;
Amended Eff. January 1, 2008; April 1, 2005; August 1, 2004; August 1, 1998; September 1, 1993; May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017;
Amended Eff. January 1, 2018.

SECTION .2300 - PRESCRIPTION INFORMATION AND RECORDS

21 NCAC 46 .2301 PRESCRIPTION: DRUG ORDER REQUIREMENTS

(a) Prescription orders shall include, but not be limited to:

(1) date of issuance;

(2) name and address of patient;

(3) name, address and telephone number of prescriber except that indication of the name of the prescriber is sufficient if a data file specified in (b) of this Rule is current and in effect;

(4) Drug Enforcement Agency (DEA) number of prescriber in the case of controlled substances;

(5) name, strength, dosage form and quantity of drug prescribed;

(6) refills if authorized or, in institutions, the stop date;

(7) route of administration of drug prescribed; and

(8) directions for use.

(b) Information in Subparagraphs (a)(2), (a)(3), (a)(4), (a)(6) and (a)(7) may be stored in a readily retrievable data file specifically compiled for use in the pharmacy, which is not a commercial publication, in lieu of the requirements of the named Subparagraphs.

History Note: *Authority G.S. 90-85.6(a); 90-85.32; 90-106(h);*
Eff. December 31, 1985;
Amended Eff. May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2302 RECORDS OF DISPENSING

(a) Records of dispensing for original and refill prescriptions shall be made and kept by pharmacies for three years and shall include:

(1) the quantity dispensed, if the quantity of the refill is different than the quantity of the original;

(2) the date of dispensing;

(3) the serial number (or equivalent in an institution);

(4) the identification of the pharmacist responsible for dispensing; and

(5) records of refills to date.

(b) Records in institutional pharmacies may be made and kept as part of the patient's medical record.

History Note: *Authority G.S. 90-85.6(a); 90-85.26; 90-85.30; 90-85.35; 90-106(h);*
Eff. December 31, 1985;
Amended Eff. March 1, 2013; May 1, 1989;

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

21 NCAC 46 .2303 RECORDS OF PRESCRIPTION FILLING AND REFILLING

In a pharmacy with a manual system of recordkeeping of prescription filling and refilling, the dispensing pharmacist shall indicate by date and initial the filling or refilling of a prescription on the document. In a pharmacy with an automated data processing system as provided in Rule .2304 of this Section, a designation of the dispensing pharmacist filling or refilling each prescription is required as provided in Rule .2304 of this Section. Information must be kept for three years. This does not preclude the use of unlicensed personnel entering information in a data system provided that supervision is maintained pursuant to Board rules.

History Note: *Authority G.S. 90-85.6(a); 90-85.26; 90-85.32;*
Eff. December 31, 1985;
Amended Eff. March 1, 2013; May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2304 AUTOMATED DATA PROCESSING SYSTEMS

An automated data processing system may be employed as a record-keeping system in a pharmacy if the following conditions are met:

(1) The system has the capability of producing sight-readable documents of all original and refilled prescription information. The term "sight-readable" means that a regulatory agent is able to examine the record and read the information. In administrative proceedings before the Board, records must be provided in a readable paper printout form.

(2) Information includes the prescription requirements and records of dispensing as indicated in Rules .2301 and .2302 of this Section.

(3) The individual pharmacist responsible for completeness and accuracy of the entries to the system provides documentation of the fact that prescription information entered into the computer is correct.

(4) Documentation in Item (3) of this Rule is provided in the pharmacy within 72 hours of date of dispensing.

(5) An auxiliary recordkeeping system is established for the documentation of refills if the automated data processing system is inoperative for any reason. When the automated data processing system is restored to operation, the information regarding prescriptions filled, refilled or transferred during the inoperative period shall be entered into the automated data processing system within the time equal to the number of inoperative days times three; for example, if the system were inoperative for five days then all interim data shall be entered within 15 days of the last inoperative day. However, nothing in this Item precludes the pharmacist from using professional judgment for the benefit of a patient's health and safety. The auxiliary record keeping system shall be backed up at least weekly.

(6) The pharmacy makes arrangements with the supplier of data processing services or materials to assure that the pharmacy continues to have adequate and complete prescription and dispensing records if the relationship with the supplier is terminated for any reason. A pharmacy shall assure continuity in the maintenance of records.

(7) A current version of drug interactions software is used and policies and procedures are established to address overriding the software's alerts of any drug interactions.

History Note: *Authority G.S. 90-85.6(a); 90-85.26; 90-85.32; 90-107;*
Eff. December 31, 1985;
Amended Eff. March 1, 2013; April 1, 1999; May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2305 SECURITY

To maintain the confidentiality of patients' prescription orders, there must exist adequate safeguards or security of the records.

History Note: *Authority G.S. 90-85.6(a); 90-85.36;*
Eff. December 31, 1985;
Amended Eff. May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

SECTION .2400 - DISPENSING IN HEALTH DEPARTMENT

21 NCAC 46 .2401 MEDICATION IN HEALTH DEPARTMENTS

A registered nurse employed by a local health department may dispense prescription drugs or devices under the following conditions:

(1) Drugs or devices may be dispensed only to health department patients, with the exception of:
   (a) opioid antagonists, which may be dispensed either to health department patients or to others as permitted by G.S. 90-12.7; and
   (b) epinephrine auto-injectors, which may be dispensed either to health department patients or to school personnel as permitted by G.S. 115C-375.2A;

(2) No drugs or devices may by dispensed except at health department clinics;

(3) The health department shall secure the services of a pharmacist-manager who shall be responsible for compliance with all statutes, rules, and regulations governing the practice of pharmacy and dispensing of drugs at the health department;

(4) Only the general categories of drugs or devices listed in Rule .2403 of this Section may be dispensed by a health department registered nurse; and

(5) All drugs or devices dispensed pursuant to G.S. 90-85.34A 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 verify the accuracy of the records at least weekly, and where health department personnel dispense to 30 or more patients in a 24-hour period per dispensing site, the pharmacist-manager shall verify the accuracy of the records within 24 hours after dispensing occurs.

History Note: *Authority G.S. 90-12.7; 90-85.6; 90-85.34A; 115C-375.2A;*
Eff. March 1, 1987;
Amended Eff. September 1, 2016; January 1, 2015; August 1, 2014; May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2402 TRAINING OF HEALTH DEPARTMENT NURSES

(a) No registered nurse may dispense drugs or devices or perform any duties pursuant to G.S. 90-85.34A prior to satisfactory completion of training acceptable to the Board. The Board may require registered nurses to complete additional training regarding substantive changes in the law governing labelling and packaging of prescription drugs and devices.

(b) Proposed curricula for initial training for registered nurses secured by health departments must be submitted to the Board for its approval no later than 60 days prior to the date training is to commence. No registered nurses may be enrolled in any such proposed training course until written Board approval is obtained. Initial training must include, but need not be limited to, instruction in labelling and packaging of prescription drugs and devices.

(c) Written proposals shall be sent to the Board's offices, and shall include the following information:

(1) description of topics or courses to be covered;

(2) instructor for each topic or course, and his or her qualifications and credentials;

(3) anticipated duration of each topic or course.

History Note: *Authority G.S. 90-85.6; 90-85.34A;*
Eff. March 1, 1987;
Amended Eff. May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2403 DRUGS AND DEVICES TO BE DISPENSED

History Note: *Authority G.S. 90-12.7; 90-85.6; 90-85.34A; 115C-375.2A;*
Eff. March 1, 1987;
Amended Eff. September 1, 2016; January 1, 2015; August 1, 2014; May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017;
Amended Eff. March 1, 2019;
Repealed Eff. October 1, 2022.

SECTION .2500 - MISCELLANEOUS PROVISIONS

21 NCAC 46 .2501 SUPERVISION

In order to properly exercise the supervision of unlicensed personnel required by these rules, the responsible pharmacist must physically review the prescription order and the dispensed product before the product is delivered to the patient or person acting on the patient's behalf.

History Note: *Authority G.S. 90-85.6; 90-85.40(a);*
Eff. May 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

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) 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 all access 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, the pharmacy shall be secured to prohibit unauthorized entry.

(f) These duties shall be in addition to the duties of pharmacist-managers as set forth in the other rules in this Chapter.

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

(1) 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 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.

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. November 1, 2021; March 1, 2019.

21 NCAC 46 .2503 RESEARCH PARTICIPATION

History Note: *Authority G.S. 90-85.3(r); 90-85.6;*
Eff. May 1, 1989;
Expired Eff. November 1, 2017 pursuant to G.S. 150B-21.3A.

21 NCAC 46 .2504 PATIENT COUNSELING
(a) "Patient Counseling" shall mean the effective communication of information, as defined in this Rule, to the patient or representative in order to improve therapeutic outcomes by maximizing proper use of prescription medications, devices, and medical equipment. All provisions of this Rule shall apply to device and medical equipment permit holders, except Subparagraph (a)(8) of this Rule and except where otherwise noted. Specific areas of patient counseling include, but are not limited to, those matters listed in this Rule that in the exercise of the pharmacist's or device and medical equipment permit holder's professional judgment are considered significant:

(1) name, description, and purpose of the medication;
(2) route, dosage, administration, and continuity of therapy;
(3) special directions for use by the patient;
(4) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
(5) techniques for self-monitoring drug therapy;
(6) proper storage;
(7) prescription refill information; and
(8) action to be taken in the event of a missed dose.

(b) An offer to counsel shall be made on new or transfer prescriptions at the time the prescription is dispensed or delivered to the patient or representative. Ancillary personnel may make the offer to counsel, but the pharmacist must personally conduct counseling if the offer is accepted. Counseling by device and medical equipment permit holders must be conducted by personnel proficient in explaining and demonstrating the safe and proper use of devices and equipment. The person in charge shall be responsible for ensuring that all personnel conducting counseling are proficient in explaining and demonstrating the safe and proper use of devices and equipment and for documenting the demonstration of such proficiency. The offer shall be

made orally and in person when delivery occurs at the pharmacy. When delivery occurs outside of the pharmacy, whether by mail, vehicular delivery or other means, the offer shall be made either orally and in person, or by telephone from the pharmacist to the patient. If delivery occurs outside of the pharmacy, the pharmacist shall provide the patient with access to a telephone service that is toll-free for long-distance calls. A pharmacy whose primary patient population is accessible through a local measured or toll-free exchange need not be required to offer toll-free service. Counseling may be conducted by the provision of printed information in a foreign language if requested by the patient or representative. Professional judgment shall be exercised in determining whether or not to offer counseling for prescription refills. An offer to counsel shall be communicated in a positive manner to encourage acceptance.

(c) In order to counsel patients effectively, a reasonable effort shall be made to obtain, record, and maintain significant patient information, including:

(1) name, address, telephone number;
(2) date of birth (age), gender;
(3) medical history:
    (A) disease state(s);
    (B) allergies/drug reactions;
    (C) current list on non-prescription and prescription medications, devices, and medical equipment.
(4) comments relevant to the individual's drug therapy.

A "reasonable effort" shall mean a good faith effort to obtain from the patient or representative the foregoing patient information. Ancillary personnel may collect, record, and obtain patient profile information, but the pharmacist or person in charge of the facility holding the device and medical equipment permit must review and interpret patient profile information and clarify confusing or conflicting information. Professional judgment shall be exercised as to whether and when individual patient history information should be sought from other health care providers.

(d) Once patient information is obtained, this information shall be reviewed and updated by the pharmacist or person in charge of the facility holding the device and medical equipment permit before each prescription is filled or delivered, typically at the point-of-sale or point of distribution to screen for potential drug therapy problems due to:

(1) therapeutic duplication;
(2) drug-disease contraindication;
(3) drug-drug interactions, including serious interactions with prescription or over-the-counter drugs;
(4) incorrect drug dosage or duration of drug treatment;
(5) drug-allergy interactions; and
(6) clinical abuse/misuse.

(e) Unless refused by the patient or representative, patient counseling shall be provided as follows:

(1) counseling shall be "face to face" by the pharmacist, or personnel of a device and medical equipment permit holder when possible;
(2) alternative forms of patient information may be used to supplement patient counseling;
(3) patient counseling, as described in this Rule, shall be required for outpatient and discharge patients of hospitals, health maintenance organizations, health departments, and other institutions; however, compliance with this Rule in locations in which non-pharmacists are authorized by law or regulations to dispense may be accomplished by such authorized non-pharmacists; and
(4) patient counseling, as described in this Rule, shall not be required for inpatients of hospitals or other institutions where a nurse or other licensed health care professional administers the medication(s).

(f) Pharmacists that distribute prescription medication by mail, and where the practitioner-pharmacist-patient relationship does not exist, shall provide counseling services for recipients of such medication in accordance with this Rule.

(g) Records resulting from compliance with this Rule, including documentation of refusals to receive counseling, shall be maintained for three years in accordance with Section .2300 of this Chapter.

(h) Personnel of device and medical equipment permit holders shall give written notice of warranty, if any, regarding service after the sale. The permit holder shall maintain documentation demonstrating that the written notice of warranty was given to the patient.

(i) Offers to counsel and patient counseling for inmates need not be "face to face", but rather, may be conducted through a correctional or law enforcement officer or through printed material. A pharmacist or a device and medical equipment permit holder dispensing drugs or devices or delivering medical equipment to inmates need not comply with Paragraph (c) of this Rule. However, once such patient information is obtained, the requirements of Paragraph (d) of this Rule shall be followed.

History Note: *Authority G.S. 90-85.6; 90-85.22; 90-85.32; 42 U.S.C. 1396r-8(g);*
Eff. January 4, 1993;

Amended Eff. June 1, 2004; July 1, 1996; September 1, 1995;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2505 VETERINARY PRESCRIPTION DRUGS

A drug that under federal law is required, prior to being dispensed, to be labeled with the statement: "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" may be dispensed only by a licensed veterinarian or by a pharmacist from a pharmacy pursuant to prescription or order of a licensed veterinarian.

History Note: *Authority G.S. 90-85.3; 90-85.6;*
Eff. September 1, 1995;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2506 EXCEPTIONS TO HEALTH CARE PRACTITIONERS IDENTIFICATION REQUIREMENTS

(a) A pharmacist is not required to wear a readily visible badge or other form of identification in the following direct patient care situations:

(1) procedures requiring full sterile dress; or
(2) procedures requiring other protective clothing or covering.

(b) Identification of a pharmacist may be limited to first name only with reference to licensure or other professional designation when the full name identification may:

(1) place the personal safety of the pharmacist in jeopardy; or
(2) interfere with the therapeutic relationship between the pharmacist and client(s).

History Note: *Authority G.S. 90-640;*
Eff. August 1, 2002;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2507 ADMINISTRATION OF VACCINES BY PHARMACISTS

(a) An Immunizing Pharmacist shall administer only those vaccines or immunizations permitted by G.S. 90-85.15B and shall do so subject to all requirements of that statute and this Rule.

(b) The following words and terms, when used in this Rule, have the following meanings:

(1) "Administer" means the direct application of a drug to the body of a patient by injection, inhalation, ingestion, or other means by:
    (A) an Immunizing Pharmacist;
    (B) a Pharmacy Intern or registered pharmacy technician who is under the supervision of an Immunizing Pharmacist; or
    (C) the patient at the direction and under the direct, in-person supervision of either an Immunizing Pharmacist or a health care provider authorized by North Carolina law to prescribe the vaccine.
(2) "Immunizing Pharmacist" shall have the meaning provided in G.S. 90-85.3(i1).
(3) "Immunizing Pharmacy Personnel" means an Immunizing Pharmacist, or a Pharmacy Intern or a registered pharmacy technician who administers vaccines under the supervision of an Immunizing Pharmacist.
(4) "Pharmacy Intern" shall have the meaning provided in 21 NCAC 46 .1317(16).
(5) "Physician" means an M.D. or D.O. currently licensed with the North Carolina Medical Board who is responsible for the supervision of the Immunizing Pharmacist pursuant to the Written Protocol between the Immunizing Pharmacist and the Physician.
(6) RESERVED
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(12) "Written Protocol" is a document prepared, signed, and dated by the Physician and Immunizing Pharmacist that shall contain the following:
    (A) the name of the Physician responsible for authorizing the Written Protocol;
    (B) the name of the Immunizing Pharmacist authorized to administer vaccines;

(C) the immunizations or vaccinations that may be administered by the Immunizing Pharmacist;
(D) the screening questionnaires and safety procedures that shall at least include the then-current minimum standard screening questionnaire and safety procedures adopted by the Medical Board, the Board of Nursing, and the Board of Pharmacy pursuant to S.L. 2013-246, s. 6, and available at the Board of Pharmacy's office and on its website (www.ncbop.org).
(E) the procedures to follow, including any drugs required by the Immunizing Pharmacist for treatment of the patient, in the event of an emergency or adverse event following vaccine administration;
(F) the reporting requirements by the Immunizing Pharmacist to the Physician, including content and time frame; and
(G) the locations at which the Immunizing Pharmacist may administer immunizations or vaccinations.

The Physician and the Immunizing Pharmacist shall review the Written Protocol at least annually and revise it if necessary.

(c) A registered pharmacy technician may administer those vaccines or immunizations permitted by G.S. 90-85.15B on behalf of an Immunizing Pharmacist, if the registered pharmacy technician does the following:

(1) Completes a practical training program that is approved by the Accreditation Council of Pharmacy Education;
(2) Holds a current basic CPR certification;
(3) Notifies the North Carolina Board of Pharmacy of immunizing pharmacy technician status;
(4) Is supervised by an Immunizing Pharmacist who is responsible for ensuring compliance with all legal requirements for vaccinations administered by a registered pharmacy technician under this Rule;
(5) Either (i) has an Immunizing Pharmacist on site and readily available to assist as needed, or (ii) has another licensed health care provider authorized to administer vaccines on site and readily available to assist as needed and has a supervising pharmacist readily available by phone or other telecommunications method for consultation as needed;
(6) Has the Immunizing Pharmacist or other health care provider who is present under Subparagraph (5) of this Paragraph review the patient's vaccine registry or other vaccination records and the screening questionnaire before the pharmacy technician administers the vaccine;
(7) Makes an offer of counseling in compliance with Rule .2504 of this Section; and
(8) Maintains documentation of three hours of immunization-related continuing education approved by the Accreditation Council for Pharmacy Education every two years.

(d) Immunizing Pharmacy Personnel who, because of physical disability, are unable to obtain a current CPR certification pursuant to G.S. 90-85.3(i1)(1), may administer vaccines in the presence of a pharmacy technician, Pharmacy Intern, or pharmacist who holds a current provider level CPR certification.

(e) With each dose of vaccine, the Immunizing Pharmacy Personnel shall give the most current vaccine information regarding the purpose, risks, benefits, and contraindications of the vaccine to the patient or legal representative. The Immunizing Pharmacy Personnel must ensure that the patient or legal representative has the opportunity to read, or to have read to him or her, the information provided and to have any questions answered prior to administration of the vaccine.

(f) In agreeing to serve as a supervising Physician, the Physician shall agree to meet the following requirements:

(1) be responsible for the formulation or approval of the Written Protocol and review the Written Protocol and the services provided to patients under the Written Protocol, as set out in Subparagraph (b)(12) of this Rule;
(2) be accessible to the Immunizing Pharmacist or be available through direct telecommunication for consultation, assistance, direction, and provide back-up coverage; and
(3) receive periodic status reports from the Immunizing Pharmacist, including any problems or complications encountered.

(g) The following requirements pertain to drugs administered by Immunizing Pharmacy Personnel:

(1) Drugs administered under the provisions of this Rule shall be in the legal possession of:
(A) a pharmacy, which shall be the pharmacy responsible for drug accountability, including the maintenance of records of administration of the immunization or vaccination; or
(B) the Physician, who shall be responsible for drug accountability, including the maintenance of records of administration of the immunization or vaccination;
(2) Drugs shall be transported and stored at the proper temperatures indicated for each drug;
(3) Immunizing Pharmacy Personnel, while engaged in the administration of vaccines under the Written Protocol, shall have in their custody and control the vaccines identified in the Written Protocol and any other drugs listed in the Written Protocol to treat adverse events; and

(4) After administering vaccines at a location other than a pharmacy, the Immunizing Pharmacy Personnel shall return all unused prescription medications to the pharmacy or Physician responsible for the drugs.

(h) Record Keeping and Reporting.

(1) An Immunizing Pharmacist shall maintain the following information, readily retrievable, in the pharmacy records in accordance with the applicable rules and statute regarding each administration:
- (A) the name, address, and date of birth of the patient;
- (B) the date of the administration;
- (C) the administration site of injection (e.g., right arm, left leg, right upper arm);
- (D) route of administration of the vaccine;
- (E) the name, manufacturer, lot number, and expiration date of the vaccine;
- (F) dose administered;
- (G) the name and address of the patient's primary health care provider, as identified by the patient; and
- (H) the name or identifiable initials of the Immunizing Pharmacist.

(2) An Immunizing Pharmacist shall document the annual review with the Physician of the Written Protocol as required in this Rule.

(3) An Immunizing Pharmacist shall report adverse events associated with administration of a vaccine to either the prescriber, when administering a vaccine pursuant to G.S. 90-85.15B(a), or the patient's primary care provider, if the patient identifies one, when administering a vaccine pursuant to G.S. 90-85.15B(b).

(i) The Immunizing Pharmacist shall maintain written policies and procedures for handling and disposal of used or contaminated equipment and supplies.

(j) The Immunizing Pharmacist shall comply with Rule .1820 of this Chapter in the practice of pharmacy pursuant to this Rule.

History Note: *Authority G.S. 90-85.3; 90-85.6; 90-85.15B; S.L. 2021-110, s. 4.(a) and (b);*
Eff. April 1, 2003;
Emergency Amendment Eff. May 11, 2004;
Temporary Amendment approved by RRC October 21, 2004;
Amended Eff. February 1, 2008; November 1, 2005; November 1, 2004;
Emergency Amendment Eff. October 9, 2009;
Temporary Amendment Eff. December 29, 2009;
Amended Eff. September 1, 2014; March 1, 2012;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017;
Amended Eff. March 1, 2023; July 1, 2022; June 1, 2020.

21 NCAC 46 .2508 ELECTRONIC RECORDS

Unless otherwise specified in the rules in this Section or other applicable law, any documentation required by the rules in this Section may be electronically created and maintained, provided that the system that creates and maintains the electronic record:

(1) is capable of printing the documentation so that the pharmacist-manager can provide it to the Board within 48 hours of a request;

(2) contains security features to prevent unauthorized access to the records; and

(3) contains daily back-up functionality to protect against record loss.

History Note: *Authority G.S. 90-85.6; 90-85.26; 90-85.30; 90-85.32; 90-85.33; 90-85.35; 90-85.36; 90-85.47; 90-106; 90-107;*
Eff. March 1, 2013;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2509 AVAILABILITY OF PHARMACY RECORDS

A pharmacist may disclose pharmacy records to investigators of occupational licensing boards whose licensees have prescribing authority during the course of an investigation of such licensee as permitted by state or federal law.

History Note: *Authority G.S. 90-85.6; 90-85.36;*
Eff. March 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2510 WAIVER OF ENFORCEMENT

The Board may waive the enforcement of specific rules under the following circumstances:

(1) The departure from ordinary practice is designed to have a positive impact on the delivery of pharmaceutical care or designed to reduce healthcare expenditures;

(2) Patient health and safety are not compromised by the waiver;

(3) A policy and procedure manual detailing the type and method of operation, hours of operation, and method of documentation of continuing pharmacist control accompanies the application; and

(4) The waiver is subject to continuing compliance with the conditions approved by the Board.

History Note: *Authority G.S. 90-85.6; 90-85.34; 150B-19(6);*
Eff. July 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2511 CHARGE FOR STATUS AFFIDAVIT

The Board shall charge persons requesting a verified duplicate copy of any license, permit, or registration a fee of twenty-five dollars ($25.00). The Board shall furnish such affidavits free of charge to governmental entities.

History Note: *Authority G.S. 90-85.24(a)(16);*
Eff. March 1, 2006;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2512 PHARMACIST WORK CONDITIONS

A permit holder shall not require a pharmacist to work longer than 12 continuous hours per work day. A pharmacist working longer than six continuous hours per work day shall be allowed during that time period to take a 30 minute meal break and one additional 15 minute break.

History Note: *Authority G.S. 90-85.2; 90-85.6(a); 90-85.21(a); 85-32(a);*
Eff. April 1, 2007;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2513 DRUG, SUPPLIES AND MEDICAL DEVICE REPOSITORY PROGRAM

(a) This Rule establishes the Drug, Supplies and Medical Device Repository Program as specified in G.S. 90-85.44.

(b) Definitions. Any term defined in G.S. 90-85.44(a) shall have the same definition under this Rule.

(c) Requirements For a Pharmacy to Participate in Accepting and Dispensing Donated Drugs, Supplies and Medical Devices.

(1) Any pharmacy or free clinic holding a valid, current North Carolina pharmacy permit may accept and dispense donated drugs, supplies and medical devices in accordance with the requirements of this Rule and G.S. 90-85.44.

(2) A dispensing physician registered with the Board in compliance with G.S. 90-85.21(b) and providing services to patients of a free clinic that does not hold a pharmacy permit may accept and dispense donated drugs, supplies and medical devices in accordance with the requirements of this Rule and G.S. 90-85.44.

(3) A participating pharmacy or dispensing physician shall notify the Board in writing of such participation at the time participation begins and annually on its permit or registration renewal application.

(4) A participating pharmacy or dispensing physician that ceases participation in the program shall notify the Board in writing within 30 days of doing so and shall submit a written report detailing the final disposition of all donated drugs, supplies and medical devices held by the participating pharmacy or dispensing physician.

(d) Drugs, Supplies and Medical Devices Eligible for Donation.

(1) A participating pharmacy or dispensing physician may accept donation of a drug, supply or medical device meeting the criteria specified in G.S. 90-85.44(c).

(2) The following categories of drugs, supplies and medical devices shall not be accepted by a participating pharmacy or dispensing physician:

(A) A controlled substance, unless acceptance of a donated controlled substance is authorized by federal law.

(B) Any prescription drug or medical device subject to a restricted distribution system mandated by the United States Food and Drug Administration.

(C) Biologicals, unless donated by the manufacturer or a prescription drug wholesaler. A pharmacy may donate a biological if the biological has been stored according to the manufacturer's labeling and has not previously been dispensed to a patient or other person.

(D) Compounded drugs or parenteral admixtures.

(E) Any drug requiring refrigerated storage, unless donated by either (a) the manufacturer, (b) a prescription drug wholesaler or (c) a pharmacy that has stored the drug according to the manufacturer's labeling and has not previously dispensed the drug to a patient or other person.

(e) Required Records.

(1) A participating pharmacy or dispensing physician that dispenses donated drugs, supplies or medical devices to an eligible patient shall maintain a written or electronic inventory of each donated drug, supply and medical device that shall include the following:

(A) The name, strength, dosage form, number of units, manufacturer's lot number and expiration date.

(B) The name, address and phone number of the eligible donor providing each drug, supply or medical device.

(2) A participating pharmacy or dispensing physician shall keep all donated drugs, supplies and medical devices physically separated from other inventory. The physically separate storage area for donated drugs, supplies and medical devices shall be identified.

(3) In addition to all records required for dispensing a prescription drug, supply or medical device under the North Carolina Pharmacy Practice Act and rules, a participating pharmacy or dispensing physician that dispenses donated drugs, supplies or medical devices to an eligible patient shall note – either on the face of a written prescription or in the electronic record of a prescription – that a donated prescription drug, supply or medical device was dispensed to the patient.

(4) A participating pharmacy or dispensing physician that dispenses donated drugs, supplies or medical devices to an eligible patient shall maintain patient-specific written or electronic documentation of any dispensing of a donated non-prescription drug, supply or medical device.

(f) Eligible Patient.

(1) A participating pharmacy or dispensing physician shall establish and maintain a written patient eligibility policy that shall conform to the priorities specified in G.S. 90-85.44(f).

(2) Donated drugs, supplies or medical devices shall be dispensed to patients who are residents of North Carolina and meet the participating pharmacy's or dispensing physician's eligibility criteria.

(g) Handling Fee.

(1) A participating pharmacy or dispensing physician may charge a prescription drug handling fee to an eligible patient that shall not exceed the co-payment established by North Carolina Medicaid and required of a North Carolina Medicaid beneficiary who receives the same prescription drug in the same quantity.

(2) A participating pharmacy or dispensing physician may charge a medical device or supply handling fee to an eligible patient that shall not exceed the co-payment established by North Carolina Medicaid and required of a North Carolina Medicaid beneficiary to whom a brand-name prescription drug is dispensed.

(3) Nothing in this Rule shall require a participating pharmacy or dispensing physician to charge an eligible patient a handling fee, nor shall a participating pharmacy or dispensing physician charge a handling fee where doing so is otherwise prohibited by law.

(h) Confidentiality of Records.

(1) A participating pharmacy or dispensing physician that dispenses donated drugs, medical devices or supplies to an eligible patient shall remove or alter any labeling or other material from a donated drug, supply or medical device that could identify the patient to whom the donated product was originally dispensed so that the identity of that patient cannot be determined.

(2) Records required by this Rule shall be governed by the confidentiality provisions of G.S. 90-85.36 and the Health Insurance Portability and Accountability Act of 1996.

(3) Records required by this Rule shall be maintained by the participating pharmacy or dispensing physician for a period of three years.

History Note: *Authority G.S. 90-85.6; 90-85.26; 90-85.32; 90-85.44;*
Eff. June 1, 2010;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2514 ADMINISTRATION OF LONG-ACTING INJECTABLES

(a) A "long-acting injectable" is drug product formulated to produce sustained release and gradual absorption of the active pharmaceutical ingredient over an extended period of time after administration by subcutaneous or intramuscular injection.

(b) "Administer" means the direct application of a drug to the body of a patient by injection by:

(1) an Immunizing Pharmacist;

(2) a pharmacy intern who is under the direct, in-person supervision of an Immunizing Pharmacist; or

(3) the patient at the direction and under the direct, in-person supervision of either an Immunizing Pharmacist or a health care provider authorized by North Carolina law to prescribe the long-acting injectable.

(c) In order to administer long-acting injectables, an Immunizing Pharmacist must:

(1) satisfy all requirements to be an "Immunizing Pharmacist" under G.S. 90-85.3(i1);

(2) document training on administering long-acting injectables both subcutaneously and intramuscularly. This training may include a program accredited by the American Council on Pharmaceutical Education (ACPE) or the North Carolina Association of Pharmacists, curriculum based programs from an ACPE-accredited school of pharmacy, state or local health department programs, or training by a health care practitioner with experience in administering long-acting injectables;

(3) notify the Board of the status as both an Immunizing Pharmacist and a pharmacist who administers long-acting injectables; and

(4) administer long-acting injectables in accordance with G.S. 90-85.15B, as well as all other pertinent State and federal laws and regulations (including but not limited to U.S. Food and Drug Administration Risk Evaluation and Mitigation Strategies).

(d) An Immunizing Pharmacist who, because of physical disability, is unable to obtain a current provider level CPR certification pursuant to G.S. 90-85.3(i1)(1), may administer long-acting injectables in the presence of a pharmacy technician or pharmacist who holds a current provider level CPR certification.

(e) Before each administration of a long-acting injectable, the Immunizing Pharmacist must personally and affirmatively conduct patient counseling that complies with Rule .2504 of this Chapter.

(f) The following requirements pertain to long-acting injectables administered by an Immunizing Pharmacist:

(1) Drugs administered by an Immunizing Pharmacist under the provisions of this Rule shall be in the legal possession of:

(A) a pharmacy, which shall be the pharmacy responsible for drug accountability, including the maintenance of records of administration of the long-acting injectable; or

(B) a prescriber, who shall be responsible for drug accountability, including the maintenance of records of administration of the long-acting injectable.

(2) Drugs shall be transported and stored at the proper temperatures indicated for each drug.

(3) Immunizing Pharmacists, while engaged in the administration of long-acting injectables, shall have in their custody and control drugs needed to treat adverse events.

(4) After administering long-acting injectables at a location other than a pharmacy, the Immunizing Pharmacist shall return all unused prescription medications to the pharmacy or prescriber responsible for the drugs.

(g) Record Keeping and Reporting.

(1) An Immunizing Pharmacist shall maintain the following information, readily retrievable, in the pharmacy records in accordance with the applicable rules and statute regarding each administration of a long-acting injectable:

(A) the name, address, and date of birth of the patient;

(B) the date of the administration;

(C) the administration site of injection (e.g., right arm, left leg, right upper arm);

(D) route of administration of the drug;

(E) the name, manufacturer, lot number, and expiration date of the drug;

(F) dose administered;

(G) the name and address of the prescriber; and

(H) the name or identifiable initials of the Immunizing Pharmacist.

(2) An Immunizing Pharmacist shall report to the prescriber adverse events associated with administration of a long-acting injectable.

(h) The Immunizing Pharmacist shall maintain written policies and procedures for handling and disposal of used or contaminated equipment and supplies.

History Note: *Authority G.S. 90-85.3; 90-85.6; 90-85.15B;*
Temporary Adoption Eff. October 1, 2021;
Eff. July 1, 2022.

21 NCAC 46 .2515 REMOTE WORK BY PHARMACY PERSONNEL

(a) Pharmacy personnel may perform pharmacy practice remotely with respect to drugs, devices, or medical equipment dispensed by the permitted pharmacy location by which they are employed. Pharmacy personnel may not engage in physical acts in the dispensing process in remote locations outside the permitted pharmacy location. The pharmacist-manager must ensure that pharmacy personnel are able to perform at the same level of competence, attention, and proficiency as if the personnel were physically present in the pharmacy, including having secure access to the pharmacy's information system, and that all applicable state and federal laws, rules, and regulations are followed.

(b) Out-of-state permit holders may permit remote pharmacy practice by their own employees with respect to drugs, devices, or medical equipment dispensed by those pharmacy locations into the State of North Carolina only to the extent permitted by the laws of the states in which they are located.

(c) This Rule does not include services provided by someone who is not an employee of the permitted pharmacy location that is dispensing the drug, device, or medical equipment. Any such remote medication order entry services are governed by Rule .1816 of this Chapter.

History Note: *Authority G.S. 90-85.6; 90-85.21; 90-85.21A; 90-85.26; 90-85.32; 90-85.34;*
Eff. May 1, 2022.

SECTION .2600 – DEVICES

21 NCAC 46 .2601 DISPENSING AND DELIVERY

(a) Devices, as defined in G.S. 90-85.3(e), shall be dispensed only in a pharmacy as defined in G.S. 90-85.3(q) or other place registered with the Board pursuant to G.S. 90-85.22. Medical equipment, as defined in G.S. 90-85.3(l1) shall be delivered only by a pharmacy as defined in G.S. 90-85.3(q) or other place registered with the Board pursuant to G.S. 90-85.22. Devices dispensed in hospitals and medical equipment delivered by hospitals are presumed to be the responsibility of the hospital pharmacy unless otherwise registered. This Rule shall apply only to entities engaged in the regular activity of delivering medical equipment.

(b) A pharmacy dispensing and delivering devices and medical equipment and not holding a device and medical equipment permit shall operate its device and medical equipment business at the same physical location as the pharmacy and through the same legal entity that holds the pharmacy permit. The pharmacist-manager shall be responsible for the dispensing and delivery of devices and medical equipment.

(c) Device and medical equipment permits shall not be issued to applicants located on residential property.

History Note: *Authority G.S. 90-85.3(e), (l1), (r); 90-85.6; 90-85.22;*
Eff. October 1, 1990;
Amended Eff. March 1, 2006; March 1, 2004; October 1, 1995;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2602 ORDERS

Devices as defined in G.S. 90-85.3(e), shall be dispensed to outpatients only pursuant to an order from a practitioner. Such orders shall comply in all pertinent respects with G.S. 106-134.1(a) and (b). Use of devices for outpatients shall be in compliance with G.S. 90-85.3(t).

History Note: *Authority G.S. 90-85.3(e),(r); 90-85.6; 90-85.22;*
Eff. October 1, 1990;
Amended Eff. April 1, 1997;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2603 EDUCATION AND TRAINING

Persons, other than pharmacists, who are authorized to dispense devices and who dispense devices shall demonstrate to the Board's satisfaction that they have received sufficient education and training in dispensing devices so that they can safely and properly dispense devices. Persons, other than pharmacists, who are authorized to deliver medical equipment and who deliver

medical equipment shall demonstrate to the Board's satisfaction that they have received sufficient education and training in the delivery of medical equipment so that they can safely and properly deliver medical equipment.

History Note: *Authority G.S. 90-85.3(e), (l1), (r); 90-85.6; 90-85.22;*
Eff. October 1, 1990;
Amended Eff. September 1, 1995;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2604 RECORDS

(a) All orders and records for devices and medical equipment shall conform in all pertinent respects with Board Rules .2301 through .2305 of this Chapter and shall be maintained at the dispensing site. In addition to the requirements of those rules, the serial numbers for all devices dispensed and all medical equipment delivered to outpatients shall be preserved as part of the records; provided, that this requirement shall not apply to disposable devices and medical equipment.

(b) All prescriptions and refill orders for devices and medical equipment shall be maintained at the dispensing site for at least three years.

(c) All device and medical equipment permit holders shall maintain a file copy of every item sold or rented with a serial number or tracking number or code in compliance with FDA Medical Device Tracking requirements.

History Note: *Authority G.S. 90-85.3(e),(l1),(r); 90-85.6; 90-85.22;*
Eff. October 1, 1990;
Amended Eff. April 1, 1999; September 1, 1995;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2605 REGISTRATION OF NON-PHARMACISTS

(a) Registration of persons other than pharmacists dispensing devices or delivering medical equipment, pursuant to G.S. 90-85.22, shall be issued by the Board to the person in charge of the location dispensing the devices or delivering medical equipment. This person shall have responsibilities comparable to those of a pharmacist-manager pursuant to Board Rule .2502 of this Chapter, as applicable. Persons in charge shall keep on file for three years on the premises of each place where devices are dispensed or medical equipment is delivered all information related to warranties provided by manufacturers and the availability of repairs; provided, that this requirement shall not apply to disposable devices and medical equipment. A person shall be in charge of only one location.

(b) A person in charge shall not:

(1) commit a felony;

(2) commit any act as a principal in a business entity that causes such entity to be excluded from participation in a federal or state program.

If a person in charge commits the conduct set out in Paragraphs (b)(1) and (b)(2) of this Rule while he or she is a person in charge, he or she shall no longer serve as a person in charge for the existing permit or for any other device and medical equipment permit.

History Note: *Authority G.S. 90-85.3(e); (11), (r); 90-85.6; 90-85.22;*
Eff. October 1, 1990;
Amended Eff. April 1, 2004; September 1, 1995;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2606 CONVEYING WARNINGS

Persons in charge or pharmacists dispensing devices or delivering medical equipment, as defined in G.S. 90-85.22, shall be responsible for promptly conveying to patients all pertinent warnings issued by government agencies or manufacturers.

History Note: *Authority G.S. 90-85.3(e), (l1), (r); 90-85.6; 90-85.22;*
Eff. October 1, 1990;
Amended Eff. September 1, 1995;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2607 AVAILABILITY OF RECORDS

All records required to be kept by statute or rule shall be available to Board inspectors or agents as provided in Rule .1803 of this Chapter. All records, including prescription orders, equipment information, and patient counseling documentation, shall be archived in a readily retrievable manner and open for review, copying or seizure by the Board or its designated employees within 48 hours of a request for inspection for a period of three years.

History Note: *Authority G.S. 90-85.3(e),(r); 90-85.6; 90-85.22;*
Eff. October 1, 1990;
Amended Eff. February 1, 2007;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2608 DISPENSING OF MEDICAL OXYGEN

Compressed medical oxygen and liquid oxygen equipment shall be dispensed and controlled according to state and federal laws.

History Note: *Authority G.S. 90-85.3(e),(l1),(r); 90-85.6; 90-85.22;*
Eff. September 1, 1995;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2609 REHABILITATION EQUIPMENT

(a) Rehabilitation equipment suppliers shall follow the provisions of this Rule rather than the provisions of 21 NCAC 46 .2611.

(b) Rehabilitation equipment suppliers shall:

(1) Solicit information from the physician, physical therapist, occupational therapist, registered nurse and other medical or educational personnel, as to the results of their assessment and evaluation of the patient's physical, functional and associated needs as well as the specific goals to be met by the enabling technology;

(2) In consultation with the referring health professional(s), patient, patient's family and other primary care providers, delineate the appropriate choices of commercially available and custom fabricated equipment to meet the specified needs of the patient;

(3) Participate in the measurement of the patient, utilizing appropriate instruments and techniques to assure the fit and function of the selected equipment;

(4) Deliver, fit and adjust the prescribed equipment;

(5) Instruct the patient and family in the safe and proper use and care of the equipment provided;

(6) Provide service and support for the equipment delivered through knowledgeable, skilled and trained service personnel and within 72 hours, provide a response to patient requests for repair service on equipment supplied; however, such service and support need not be provided unless the patient=s account is current;

(7) Provide a specific, written statement of warranty on the equipment provided, including commercial warranties and those for adapted or custom fabricated items;

(8) Maintain liability insurance of at least one million dollars ($1,000,000) worth of coverage and when involved in the design, fabrication or substantial modification of commercially available equipment, also maintain product liability insurance; and

(9) Utilize written, quality assurance procedures including, but not limited to:

(A) Reviewing custom designed and fabricated equipment and interfacing techniques with commercial equipment to assure compatibility and safety;

(B) Understanding the properties of the materials being used in custom designed and modified equipment to assure long term durability;

(C) Documenting goals and objectives of the referring medical or education personnel, as well as short and long term effectiveness of the equipment in meeting those goals and objectives; and

(D) Documenting complaints and problems as required in Rule .1608(a)(12) of this Chapter.

History Note: *Authority G.S. 90-85.3(e),(l1),(r); 90-85.6; 90-85.22;*
Eff. September 1, 1995;
Amended Eff. April 1, 1999; April 1, 1997;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2610 MEDICAL GAS, OXYGEN AND RESPIRATORY RELATED EQUIPMENT

(a) Medical gas, oxygen and respiratory related equipment suppliers shall:

(1) Comply with all applicable home medical equipment laws of North Carolina;

(2) If transporting oxygen and other medical gases in cylinder or liquid form, comply with all current Department of Transportation rules and regulations;

(3) If transfilling medical oxygen systems, comply with Food and Drug Administration (FDA) and all state agency requirements regarding transfilling and repackaging;

(4) Demonstrate that oxygen provided in cylinder or liquid form meets minimal purity standards for medical grade oxygen;

(5) Comply with local/state fire and building laws; and

(6) Meet the following safety inspection requirements:

(A) Demonstrate that each piece of oxygen/respiratory equipment has been checked, is free of defect, and operates within the manufacturers' specifications;

(B) Refrain from modifying equipment to the extent that the modification might reasonably cause harm;

(C) Maintain all electrical components so that they do not present a fire or shock hazard; and

(D) Ensure that all appropriate warning labels or labeling, including tags, are present on the equipment provided.

(b) Medical gas, oxygen and respiratory related equipment suppliers shall comply with the following recall procedures:

(1) Ensure that lot numbers and expiration dates are affixed to each cylinder delivered;

(2) Maintain a tracking system for all medical oxygen and gas delivered;

(3) Document all equipment serial numbers and model numbers to ensure that equipment can be retrieved if a recall is initiated; and

(4) Maintain records for equipment that requires FDA tracking.

(c) Medical gas, oxygen and respiratory related equipment suppliers shall comply with the following maintenance and cleaning requirements:

(1) Maintain documentation demonstrating that a function and safety check of equipment was performed prior to set up;

(2) Maintain an established protocol for cleaning and disinfecting equipment which addresses both aerobic and anaerobic pathogens;

(3) Maintain a Material Safety Data Sheet (MSDS) on file for solutions and products used in cleaning and disinfecting procedures;

(4) Maintain segregated areas on the premises and in delivery vehicles for clean, dirty, and contaminated equipment;

(5) Clean and disinfect equipment according to manufacturers' specifications; and

(6) Instruct the patient on proper cleaning techniques as specified by the manufacturer.

(d) Medical gas, oxygen and respiratory related equipment suppliers shall implement a comprehensive preventative maintenance program which includes the following:

(1) Procedures for problem reporting, tracking, recall, and resolution;

(2) Performance of service as specified by the manufacturer and the documentation of such performance in the service records; and

(3) Routine inspection, service, and maintenance of equipment located in the patient's/customer's home according to manufacturers' specifications.

(e) Medical gas, oxygen and respiratory related equipment suppliers shall maintain repair logs to document repair and maintenance of equipment, including, but not limited to, oxygen concentrators, infant monitors, and mechanical ventilators. The following information shall be documented in the repair log:

(1) type of equipment;

(2) manufacturer;

(3) model;

(4) serial number;

(5) date of repair;

(6) specific repair made; and

(7) name of person or company performing the repair.

(f) Medical gas, oxygen and respiratory related equipment suppliers shall maintain testing equipment to ensure accurate calibration. Testing equipment shall be appropriate for the level of service offered. Scales used to weigh liquid oxygen reservoirs shall be properly maintained to ensure accuracy.

(g) Medical gas, oxygen, and respiratory related equipment suppliers shall implement a written procedure at each location for handling complaints and problems, which includes a complaint file documenting complaints and problems and resolutions of the complaints or problems.
(h) Medical gas, oxygen, and respiratory related equipment suppliers shall comply with the following counseling requirements:

(1) Utilize orientation checklists to review:
  (A) Instructions for use of the equipment,
  (B) Safety precautions,
  (C) Cleaning procedures,
  (D) Maintenance procedures, and
  (E) Return demonstrations on back up oxygen systems delivered;
(2) Instruct the patient about emergency and routine contact procedures; and
(3) Deliver and review written instruction materials to ensure that the patient receives adequate information in order to properly operate the equipment.

(i) A written plan of service shall be developed, implemented, and documented in the patient record. The plan of service shall include, but is not limited to, an assessment of the safety of the home environment, the caregiver or patient ability to comply with the prescription, and the caregiver or patient ability to operate and clean the equipment as instructed.

History Note: *Authority G.S. 90-85.3(e),(l1),(r); 90-85.6; 90-85.22;*
Eff. September 1, 1995;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2611 MEDICAL EQUIPMENT

(a) Medical equipment suppliers shall:

(1) Document information from the physician or other medical personnel as to the patient's specific needs to be met by the equipment delivered as well as the effectiveness of the equipment in meeting those needs;
(2) In consultation with the referring health professional(s), patient, patient's family and other primary care providers, delineate the appropriate choices of commercially available equipment to meet the specified needs of the patient;
(3) Participate in the measurement of the patient, utilizing appropriate instruments and techniques to assure the fit and function of the selected equipment;
(4) Deliver, fit and adjust the prescribed equipment;
(5) Instruct the patient or family in the safe and proper use and care of the equipment provided in compliance with Rule .2504 of this Chapter;
(6) Provide service and support for the equipment dispensed or delivered and, within 72 hours, provide a response to patient requests for repair service on equipment supplied; however, such service and support need not be provided unless the patient=s account is current;
(7) Maintain liability insurance of at least one million dollars ($1,000,000) worth of coverage;
(8) Demonstrate that each item sold or rented has been checked, is free of defect, and operates within the manufacturers' specifications;
(9) Refrain from modifying equipment to the extent that the modification might reasonably cause harm;
(10) Maintain all electrical components so that they do not present a fire or shock hazard;
(11) Ensure that all appropriate warning labels or labeling, including tags, are present on the equipment provided;
(12) Maintain documentation demonstrating that a function and safety check of equipment was performed prior to set up;
(13) Maintain an established protocol for cleaning and disinfecting equipment which addresses both aerobic and anaerobic pathogens including procedures to prevent cross-contamination; and
(14) Clean and disinfect equipment according to manufacturers' specifications.

(b) Medical equipment suppliers shall implement a preventative maintenance program for rental equipment which includes the following:

(1) Procedures for problem reporting, tracking, recall, and resolution;
(2) Performance of service as specified by the manufacturer and the documentation of such performance in the service records; and

(3) Maintain documentation of repair and maintenance of equipment. The following information shall be documented in the repair log:
(A) Type of equipment;
(B) Manufacturer;
(C) Model;
(D) Serial number;
(E) Date of repair;
(F) Specific repair made; and
(G) Name of person or company performing the repair.

(c) In addition to Section .2500 of this Chapter providers of parenteral and enteral nutrition services shall comply with the following counseling requirements:

(1) Utilize orientation checklists to review:
(A) Instructions for use of the equipment;
(B) Safety precautions;
(C) Cleaning procedures;
(D) Maintenance procedures; and
(E) Return demonstrations on equipment delivered.
(2) Instruct the patient about emergency and routine contact procedures;
(3) Deliver and review with the patient written instruction materials to ensure that the patient receives adequate information to properly operate the equipment; and
(4) A written plan of service shall be developed, implemented, and documented in the patient record. The plan of service shall include, but is not limited to, the assessment of the safety of the home environment, the caregiver or patient's ability to comply with the prescription, and the caregiver or patient's ability to operate and clean the equipment as instructed.

History Note: *Authority G.S. 90-85.3(e)(l1)(r); 90-85.6; 90-85.22;*
Eff. May 1, 1997;
Amended Eff. April 1, 1999; August 1, 1998;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2612 STORAGE OF DEVICES AND MEDICAL EQUIPMENT

(a) Devices and medical equipment shall be stored at the location holding the pharmacy or device and medical equipment permit or a location that is within 50 miles of the permitted location. Devices and medical equipment shall not be stored on residential property.

(b) A device and medical equipment storage site not holding a pharmacy or device and medical equipment permit shall not provide any devices, medical equipment, or services directly to patients. An employee of a permitted location who has been trained as required by Rule .2603 of this Chapter may travel from the permitted site to a storage site, retrieve devices or medical equipment from the storage site, and deliver devices or medical equipment to patients.

(c) Device and medical equipment storage sites shall be subject to inspection by the Board under the same standards applicable to permitted sites.

History Note: *Authority G.S. 90-85.6; 90-85.22; 90-85.32;*
Eff. March 1, 2004;
Amended Eff. November 1, 2015; February 1, 2007;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2613 DEVICES AND MEDICAL EQUIPMENT IN POSSESSION OF PERMIT HOLDERS

Dispensed devices and medical equipment in the possession of permit holders shall bear a patient-specific prescription label. Permit holders may not collect prescription drugs from a patient or caregiver, nor may a permit holder store prescription drugs on behalf of a patient or caregiver.

History Note: *Authority G.S. 90-85.6; 90-85.22; 90-85.32;*
Eff. April 1, 2007;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

SECTION .2700 - NUCLEAR PHARMACY

21 NCAC 46 .2701 REQUIREMENTS

No pharmacist shall receive, possess or dispense radioactive drugs, except in accordance with the applicable federal statutes and regulations and these Rules. The requirements of these Rules are in addition to, and not in substitution for, other applicable provisions of the regulations of any federal or state agency with authority for regulating the use and distribution of radioactive materials.

History Note: *Authority G.S. 90-85.6;*
Eff. October 1, 1990;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2702 DEFINITIONS

For purposes of these Rules, the following terms are defined as follows:

(1) Authentication of Product History. Identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other radioactive drug.

(2) Nuclear Pharmacy. A pharmacy holding a permit issued by the North Carolina Board of Pharmacy and licenses issued by the Nuclear Regulatory Commission (NRC) and other state regulatory agencies, where prescriptions for radiopharmaceutical products are filled, compounded, or dispensed.

(3) Nuclear Pharmacy Practice. A patient-oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals.

(4) Nuclear Pharmacy Technician. Any person involved in the dispensing of a radiopharmaceutical, not satisfying the definition of Qualified Licensed Professional; any such person must be registered as a Pharmacy Technician with the State Board of Pharmacy.

(5) Qualified Licensed Professional. A non-pharmacist possessing a valid license issued by the North Carolina Medical Board, the North Carolina Board of Nursing, the North Carolina Dental Board or the North Carolina Board of Veterinary Medicine, and who has sufficient training and experience to safely handle and dispense radiopharmaceuticals as defined by the respective requirements of the regulations of the NRC or the state nuclear regulatory agencies.

(6) Qualified Nuclear Pharmacist. A pharmacist currently licensed by the Board who meets the following standards:

  (a) Certification as a nuclear pharmacist by the "Board of Pharmaceutical Specialties"; or

  (b) Meets minimum standards of training for "authorized user status" of radioactive material in accordance with the licensure guide of the United States Nuclear Regulatory Commission or the appropriate state nuclear regulatory agencies as follows:

    (i) Has received a minimum of 200 contact hours of instruction in nuclear pharmacy and the safe handling and use of radioactive materials from an approved college of pharmacy, including instruction in the following areas: radiation physics and instrumentation; radiation protection; mathematics of radioactivity; radiation biology; and radiopharmaceutical chemistry; and

    (ii) Has a minimum of 500 hours of clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist.

(7) Radiopharmaceutical Quality Assurance. The performance of appropriate chemical, biological and physical tests on potential radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history and the keeping of proper records.

(8) Radiopharmaceuticals. Radioactive drugs shall include any article that exhibits spontaneous decay or disintegration of an unstable atomic nucleus, usually accompanied by the emission of ionizing radiation and any nonradioactive reagent kit or nuclide generator that is intended for use in the preparation of any such article.

(9) Radiopharmaceutical Service. The procurement, storage, handling, preparation, labeling, quality assurance testing, dispensing, delivery, record-keeping and disposal of radiopharmaceuticals and other radioactive materials.

(10) Test Assessment. Conducting quality assurance evaluation necessary to ensure the integrity of the test.

History Note: *Authority G.S. 90-85.6; 90-85.34;*
Eff. October 1, 1990;
Amended Eff. February 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2703 OBTAINING A NUCLEAR PHARMACY PERMIT

In order to obtain a nuclear pharmacy permit, the person seeking such a permit shall submit an application to the Board certifying that he or she is a pharmacist currently licensed by the Board and that he or she is a qualified nuclear pharmacist as defined in Rule .2702 of this Section. The application shall describe the location, time and manner by which the contact hours required by Rule .2702(6) of this Section were obtained by the applicant and shall be submitted under oath.

History Note: *Authority G.S. 90-85.6; 90-85.34;*
Eff. October 1, 1990;
Amended Eff. February 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2704 REQ FOR PHARMACIES PROVIDING RADIOPHARMACEUTICAL SERVICES

(a) The permit to operate a pharmacy providing radiopharmaceutical services shall be issued by the Board only to a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals shall be under the direct supervision of a qualified nuclear pharmacist. A qualified nuclear pharmacist shall be responsible for all operations of the pharmacy related to radiopharmaceutical services and shall be in personal attendance at all times that the pharmacy renders radiopharmaceutical services.

(b) In emergency situations, and in the absence of a qualified nuclear pharmacist, designated qualified licensed professionals as identified by the pharmacist-manager in established written policies and procedures may have access to the area designated as the nuclear pharmacy area, and these individuals may prepare single doses of radiopharmaceuticals for the immediate emergency only and must document such activities.

(c) The nuclear pharmacy area shall be secured from entry by unauthorized personnel as identified by the pharmacist-manager in established written policies and procedures.

(d) Nuclear pharmacies shall maintain records of acquisition, inventory and disposition of all radiopharmaceuticals in accordance with Section .2300 of this Chapter and the applicable regulations of the North Carolina Division of Radiation Protection.

(e) All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area that provides sufficient protection from radioactivity of all areas surrounding the nuclear pharmacy area. Floor plans shall be submitted and approved by the Board staff before a nuclear pharmacy permit is issued.

(f) Radiopharmaceuticals are to be dispensed only upon a prescription or medication order from a licensed medical practitioner authorized to possess, use and administer radiopharmaceuticals.

(g) The library of a nuclear pharmacy shall contain, in addition to the volumes required by Rule .1601(a)(3) of this Chapter, copies of current state and federal regulations governing the safe storage, handling, use, dispensing, transport, and disposal of radiopharmaceuticals.

(h) All pharmacies performing Radiopharmaceutical Services shall have in effect a procedures manual setting forth the procedures and policies of the pharmacy regarding Radiopharmaceutical Quality Assurance. This manual shall at all times be readily available for review by Board personnel.

(i) Permit holders must obtain licensure from the North Carolina Division of Radiation Protection and the number of that license. Copies of the Division's inspection report shall be made available upon request for inspection by Board personnel.

History Note: *Authority G.S. 90-85.6; 90-85.34;*
Eff. October 1, 1990;
Amended Eff. February 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2705 LABELING REQUIREMENTS OF RADIOPHARMACEUTICALS

(a) In addition to other labeling requirements of the Board for non-radioactive drugs described in this Chapter, the container of a radiopharmaceutical shall also be labeled with:

(1) The standard radiation symbol;

(2) The words "CAUTION - RADIOACTIVE MATERIALS";
(3) The radionuclide of the radiopharmaceutical contained therein;
(4) The chemical form of the radiopharmaceutical contained therein;
(5) The amount of radioactivity of the radiopharmaceutical contained therein and the date and time of the calibration of that radioactivity;
(6) The date and time of the expiration of the radiopharmaceutical contained therein;
(7) If the radiopharmaceutical is a liquid, the volume;
(8) If the radiopharmaceutical is a solid, the number of capsules or weight contained therein;
(9) If the radiopharmaceutical is a gas, the number of ampules, vials, or syringes contained therein;
(10) The name, address and telephone number of the nuclear pharmacy dispensing the radiopharmaceutical;
(11) The prescription or lot number; and
(12) The name of the pharmaceutical.

(b) No radiopharmaceutical may be dispensed unless a tamper-evident seal is applied and a label is affixed to the delivery container of each dose bearing the following information:

(1) The standard radiation symbol.
(2) The words "Caution - Radioactive Material."
(3) The radionuclide and chemical form.
(4) The volume if in liquid form.
(5) The requested activity and the calibration date and time.
(6) The prescription number.
(7) Labels for radiolabeled blood components and therapeutic dosages must always contain the patient's name at the time of dispensing.

Where the patient's name is not available at the time of dispensing for diagnostic dosing, a 72-hour exemption is allowed to obtain the name of the patient. No later than 72 hours after dispensing the radiopharmaceutical, the patient's name must be associated with the prescription in a readily retrievable manner and must be retained for a period of three years.

(8) The name and address of the nuclear pharmacy.
(9) The name of the end authorized user, must also be a prescriber.
(10) The lot number of the preparation.

History Note: *Authority G.S. 90-85.6; 90-85.34;*
Eff. January 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .2706 PROHIBITIONS

(a) No person shall utilize unit-dose transport containers for radioactive dosages without an effective mechanism to avoid contamination of the transport container with blood or other biohazardous substances.

(b) No person shall re-use a unit-dose transport container that has been contaminated with blood or other biohazardous substances. Any unit-dose transport container that is returned with the tamper-evident seal broken and the unit-dose syringe included must be considered to be contaminated.

History Note: *Authority G.S. 90-85.6; 90-85.34;*
Eff. January 1, 2005;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

SECTION .2800 – COMPOUNDING

21 NCAC 46 .2801 COMPOUNDING

(a) A pharmacy may dispense a compounded drug preparation to a patient only pursuant to a prescription that is valid and complies with all requirements of the law, including 21 NCAC 46 .1801. In advance of dispensing the compounded drug preparation, a pharmacy shall prepare the compounded drug preparation only:

(1) upon the pharmacy's receipt of a valid prescription order for an individual patient; or
(2) in anticipation of a prescription order based on an established history of receiving prescription orders for the compounded drug preparation. Any compounded drug preparation prepared in anticipation of a prescription order shall not be dispensed until the pharmacy receives a valid prescription order for an individual patient.

(b) Compounded drug preparations shall not be offered to other entities for resale.
(c) A pharmacy may supply compounded drug products to practitioners authorized by law to prescribe drugs for those practitioners to administer to those practitioners' patients. Such compounding for office use shall comply with applicable federal law.
(d) The preparation, labeling, and dispensing of non-sterile compounded drug preparations shall comply with the standards established by United States Pharmacopeia chapter <795>, including all United States Pharmacopeia chapters and standards incorporated into chapter <795> by reference and including all subsequent amendments and editions of the same, governing both the non-sterile compounded drug preparations and the physical and environmental conditions under which non-sterile compounded drug preparations are prepared, labeled, and dispensed.
(e) The preparation, labeling, and dispensing of sterile compounded preparations shall comply with standards established by United States Pharmacopeia chapter <797>, including all United States Pharmacopeia chapters and standards incorporated into chapter <797> by reference and including all subsequent amendments and editions of the same, governing both the sterile compounded products and the physical and environmental conditions under which sterile compounded products are prepared, labeled, and dispensed.
(f) A pharmacy that prepares, labels, or dispenses sterile compounded preparations shall maintain a reference library in the pharmacy including the current United States Pharmacopeia standards and references on the compatibility, stability, storage, handling, and preparation of compounded drugs. These references may be either hard copy or electronically accessible.
(g) In a pharmacy where compounded drug preparations are prepared, labeled, or dispensed, the pharmacist-manager or the pharmacist-manager's designated pharmacist shall be knowledgeable in the specialized functions of preparing, labeling, and dispensing compounded drug preparations. If the pharmacist-manager chooses to designate another pharmacist for this purpose, the pharmacist-manager shall notify the Board on the pharmacy's permit application and within 15 days of any change in the designation. Notwithstanding the pharmacist-manager's designation of another pharmacist as knowledgeable in the specialized functions of preparing, labeling, and dispensing compounded drug preparations, the pharmacist-manager shall be responsible for ensuring the pharmacy's compliance with all statutes, rules, and standards that govern such activities.
(h) In addition to complying with all recordkeeping and labeling requirements specified or referred to by United States Pharmacopeia chapters <795> or <797>, a pharmacy that prepares, labels, or dispenses compounded drug preparations shall create and maintain a record-keeping system that enables the pharmacy immediately upon request to identify every compounded drug preparation prepared, labeled, or dispensed in the past three years. This recordkeeping system may be created and maintained electronically in compliance with 21 NCAC 46 .2508.
(i) The pharmacist-manager of a pharmacy that prepares, labels, or dispenses compounded drug preparations shall comply with all quality assurance requirements and standards of United States Pharmacopeia chapters <795> and <797>.
(j) Between January 1 and March 31 of each year, any pharmacy permitted by the Board that has prepared, labeled, or dispensed any compounded drug (for any patient or other person, either within or outside North Carolina) during the immediately preceding calendar year shall update all information regarding its services in the National Association of Boards of Pharmacy's e-Profile Connect system at https://dashboard.nabp.pharmacy.
(k) In addition to the requirements of this Section, the compounding of radiopharmaceutical drug products shall comply with Section .2700 of this Chapter.
(l) United States Pharmacopeia chapters <795> or <797> may be inspected at the offices of the Board during its normal hours of operation. Copies also may be obtained from the U.S. Pharmacopeial Convention (www.usp.org), as a free download as of the effective date of the last amendment to this Rule.

History Note: *Authority G.S. 90-85.6; 90-85.21A; 90-85.26; 90-85.32;*
Eff. October 1, 1990;
Amended Eff. January 1, 2015; April 1, 2003;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017;
Amended Eff. August 1, 2021.

21 NCAC 46 .2802 DEFINITIONS
21 NCAC 46 .2803 REQ/PHARMACIES DISPENSING STERILE PHARMACEUTICALS
21 NCAC 46 .2804 RESPONSIBILITIES OF PHARMACIST-MANAGER
21 NCAC 46 .2805 LABELING
21 NCAC 46 .2806 RECORDS AND REPORTS
21 NCAC 46 .2807 ANTI-NEOPLASTIC AGENTS
21 NCAC 46 .2808 QUALITY ASSURANCE

History Note: *Authority G.S. 90-85.6.*
Eff. October 1, 1990;
Amended Eff. March 1, 2013; February 1, 2006; April 1, 2003; September 1, 1995;
Repealed Eff. January 1, 2015.

SECTION .2900 - PRODUCT SELECTION

21 NCAC 46 .2901 RETURN OF OUTDATED DRUGS

(a) Adequate provisions for return of outdated drugs in both full and partial containers as provided in G.S. 90-85.28(a)(5) means that drugs can be returned up to six months after the labeled expiration date for full credit or replacement. A finding by the Board that a manufacturer does not meet this standard causes that manufacturer's products to be ineligible for use in product selection.
(b) This Rule does not apply to drugs whose only Food and Drug Administration-approved indication is for use as an antidote to biological, chemical, or radiological poisoning.

History Note: *Authority G.S. 90-85.6; 90-85.28(a)(5);*
Eff. October 1, 1991;
Amended Eff. July 1, 2011;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

SECTION .3000 - DISPOSAL OF UNWANTED DRUGS

21 NCAC 46 .3001 PROCEDURE FOR DISPOSING OF DRUGS

(a) All registrants under G.S. 90-85.21 shall develop and implement policies and procedures to insure that all out-dated, improperly labeled, adulterated, damaged or unwanted drugs or drug containers with worn, illegible or missing labels are destroyed or disposed of so as to render them unusable.
(b) Any permit holder in possession of outdated, adulterated or unwanted drugs other than controlled substances may dispose or destroy such drugs by returning them to the manufacturer, by incineration at a properly permitted facility, or by any other means approved by the Board which will assure protection against unauthorized possession or use. Destructions under this Paragraph taking place at the permit holder's premises shall be witnessed by a licensed pharmacist and documented.
(c) Any permit holder in possession of any controlled substance and desiring or required to dispose of such substance may file a written request on a form provided by the Board for authority and instructions to dispose of such substance. If destruction under this Paragraph takes place at the permit holder's premises such destruction shall be jointly witnessed by at least two licensed pharmacists approved by the Board. All destructions of controlled substances shall be documented and the document shall be retained by the permit holder for a period of at least three years. Copies of the document shall be sent to the Drug Enforcement Administration.

History Note: *Authority G.S. 90-85.6; 90-85.21;*
Eff. October 1, 1993;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

SECTION .3100 – GENERAL DEFINITIONS

21 NCAC 46 .3101 CLINICAL PHARMACIST PRACTITIONER

(a) Definitions. As used in this Rule:
(1) "Medical Board" means the North Carolina Medical Board.
(2) "Pharmacy Board" means the North Carolina Board of Pharmacy.
(3) "Clinical Pharmacist Practitioner" or "CPP" means a licensed pharmacist who is approved to provide drug therapy management, including controlled substances, under the direction or supervision of a Supervising Physician pursuant to a CPP Agreement. Only a pharmacist approved by the Pharmacy Board and the Medical Board may legally identify himself as a CPP.
(4) "Supervising Physician" means a licensed physician who, by signing the CPP Agreement, is held accountable for the on-going supervision and evaluation of the drug therapy management performed by the CPP as defined in the CPP Agreement. This term includes both the Primary Supervising Physician and any Back-Up Supervising Physician.

(5) "Primary Supervising Physician" means the Supervising Physician who shall provide on-going supervision, collaboration, consultation, and evaluation of the drug therapy management performed by the CPP as defined in the CPP Agreement.

(6) "Back-Up Supervising Physician" means a Supervising Physician who shall provide supervision, collaboration, consultation, and evaluation of the drug therapy management performed by the CPP as defined in the CPP Agreement when the Primary Supervising Physician is not available.

(7) "Approval" means authorization by the Medical Board and the Pharmacy Board for a pharmacist to practice as a CPP in accordance with this Rule.

(8) "Continuing Education or CE" is defined as courses or materials which have been approved for credit by the American Council on Pharmaceutical Education.

(9) "Clinical Experience approved by the Boards" means work in a clinical pharmacy practice setting which includes experience consistent with the components listed in Parts (b)(2)(A), (B), (C), (D), (E), (H), (I), (J), (N), (O), and (P) of this Rule. Clinical experience requirements must be met only through activities separate from the certificate programs referred to in Parts (b)(1)(B) of this Rule.

(10) "CPP Agreement" means a written agreement between the CPP, Primary Supervising Physician and any Back-Up Supervising Physician by which the Supervising Physician(s) have provided written instructions to the CPP for patient-specific and disease-specific drug therapy, which may include ordering, changing, or substituting therapies or ordering tests.

(b) CPP application for approval.

(1) The requirements for application for CPP approval include that the pharmacist:

(A) has an unrestricted and current license to practice as a pharmacist in North Carolina;

(B) meets one of the following qualifications:

(i) has earned Certification from the Board of Pharmaceutical Specialties, is a Certified Geriatric Pharmacist as certified by the Commission for Certification in Geriatric Pharmacy, or has completed an American Society of Health System Pharmacists (ASHP) accredited residency program with two years of Clinical Experience approved by the Boards; or

(ii) holds the academic degree of Doctor of Pharmacy, has three years of Clinical Experience approved by the Boards, and has completed a North Carolina Center for Pharmaceutical Care (NCCPC) or American Council on Pharmaceutical Education (ACPE) approved certificate program in the area of practice covered by the CPP Agreement; or

(iii) holds the academic degree of Bachelor of Science in Pharmacy, has five years of Clinical Experience approved by the Boards, and has completed two NCCPC or ACPE approved certificate programs with at least one program in the area of practice covered by the CPP Agreement;

(C) submits the required application and fee to the Pharmacy Board;

(D) submits any information deemed necessary by the Pharmacy Board in order to evaluate the application; and

(E) has a signed CPP Agreement.

If for any reason a CPP discontinues working under an approved CPP Agreement, the CPP shall notify the Pharmacy Board in writing within 10 days, and the CPP's approval shall automatically terminate or be placed on inactive status until such time as a new application is approved in accordance with this Subchapter.

(2) All certificate programs referred to in Subpart (b)(1)(B)(i) of this Rule must contain a core curriculum, including the following components:

(A) communicating with healthcare professionals and patients regarding drug therapy, wellness, and health promotion;

(B) designing, implementing, monitoring, evaluating, and modifying or recommending modifications in drug therapy to insure effective, safe, and economical patient care;

(C) identifying, assessing, and solving medication-related problems and providing a clinical judgment as to the continuing effectiveness of individualized therapeutic plans and intended therapeutic outcomes;

(D) conducting physical assessments, evaluating patient problems, and ordering and monitoring medications and laboratory tests;

(E) referring patients to other health professionals as appropriate;

(F) administering medications;
(G) monitoring patients and patient populations regarding the purposes, uses, effects, and pharmacoeconomics of their medication and related therapy;
(H) counseling patients regarding the purposes, uses, and effects of their medication and related therapy;
(I) integrating relevant diet, nutritional, and non-drug therapy with pharmaceutical care;
(J) recommending, counseling, and monitoring patient use of non-prescription drugs, herbal remedies, and alternative medicine practices;
(K) using, ordering, and instructing on the use of devices and durable medical equipment;
(L) providing emergency first care;
(M) retrieving, evaluating, utilizing, and managing data and professional resources;
(N) using clinical data to optimize therapeutic drug regimens;
(O) collaborating with other health professionals;
(P) documenting interventions and evaluating pharmaceutical care outcomes;
(Q) integrating pharmacy practice within healthcare environments;
(R) integrating national standards for the quality of healthcare; and
(S) conducting outcomes and other research.

(3) The completed application for approval to practice as a CPP shall be reviewed by the Pharmacy Board upon verification of a full and unrestricted license to practice as a pharmacist in North Carolina. The Pharmacy Board shall:
(A) approve the application and, at the time of approval, issue a number which shall be printed on each prescription written by the CPP;
(B) deny the application; or
(C) approve the application with restrictions, in the event that restrictions are appropriate in order to protect the public health, safety, and welfare in light of the information received and reviewed in the CPP application in Subparagraph (b)(1) of this Rule.

(c) Annual Renewal.

(1) Each CPP shall register annually on or before December 31 by:
(A) verifying that the CPP holds a current Pharmacist license;
(B) submitting the renewal fee as specified in Subparagraph (j)(2) of this Rule;
(C) completing the Pharmacy Board's renewal form; and
(D) reporting continuing education credits as required by Paragraph (d) of this Rule.

(2) If the CPP has not renewed the CPP's annual registration pursuant to Subparagraph (c)(1) of this Rule within 60 days of December 31, the approval to practice as a CPP shall lapse.

(d) Continuing Education.

(1) Each CPP shall earn 35 hours of practice-relevant CE each year, approved by the Pharmacy Board.

(2) Documentation of these hours shall be kept at the CPP practice site and made available for inspection by agents of the Medical Board or Pharmacy Board.

(e) A Supervising Physician who has a CPP Agreement with a CPP shall be readily available for consultation with the CPP and, at the meetings required by Subparagraph (f)6) of this Rule, shall review each order written by the CPP.

(f) The CPP Agreement shall:

(1) be approved and signed by the Primary Supervising Physician, any Back-Up Supervising Physician, and the CPP, and a copy shall be maintained in each practice site for inspection by agents of either Board upon request;

(2) be specific in regard to the physician, the pharmacist, the patient, and the disease;

(3) specify the predetermined drug therapy, which shall include the diagnosis and product selection by the patient's physician and any modifications which may be permitted, dosage forms, dosage schedules and tests which may be ordered;

(4) prohibit the substitution of a chemically dissimilar drug product by the CPP for the product prescribed by the physician without first obtaining written consent of the physician;

(5) include a pre-determined plan for emergency services;

(6) for the first six months of the CPP Agreement include a plan and schedule for monthly meetings to discuss the operation of the CPP Agreement and quality improvement measures between the Primary Supervising Physician and CPP, and thereafter include a plan and schedule for meetings between the Primary Supervising Physician and CPP at least once every six months to discuss the operation of the CPP

Agreement and quality improvement measures. Documentation of the meetings between the CPP and the Primary Supervising Physician shall:

(A) identify clinical issues discussed and actions taken;

(B) be signed and dated by those who attended; and

(C) be retained by both the CPP and Primary Supervising Physician and be available for review by members or agents of either Board for five calendar years;

(7) require that the patient be notified of the collaborative relationship under the CPP Agreement; and

(8) be terminated when patient care is transferred to another physician and new orders will be written by the succeeding physician.

(g) A Supervising Physician shall:

(1) be fully licensed with the Medical Board and engaged in clinical practice;

(2) not be serving in a postgraduate medical training program;

(3) be approved in accordance with this Subchapter before the CPP supervision occurs; and

(4) supervise no more than three pharmacists.

(h) The CPP shall wear a nametag spelling out the words "Clinical Pharmacist Practitioner".

(i) A CPP may be censured or reprimanded, and his or her approval may be restricted, suspended, revoked, annulled, denied, or terminated by the Medical Board or the Pharmacy Board. In addition or in the alternative, the pharmacist may be censured or reprimanded, and the pharmacist's license may be restricted, suspended, revoked, annulled, denied, or terminated by the Pharmacy Board, in accordance with provisions of G.S. 150B. The Pharmacy Board or the Medical Board may take the actions set forth in this Paragraph with respect to the pharmacist, the CPP approval, or the pharmacist's license, if either Board finds one or more of the following:

(1) the CPP has held himself or herself out as, or permitted another to represent that the CPP is, a licensed physician;

(2) the CPP has engaged, or attempted to engage, in the provision of drug therapy management other than at the direction of, or under the supervision of, a physician licensed and approved by the Medical Board to be that CPP's Supervising Physician;

(3) the CPP has provided, or attempted to provide, medical management outside the approved CPP Agreement or for which the CPP is not qualified by education and training to provide;

(4) the CPP commits any act prohibited by G.S. 90-85.38 as determined by the Pharmacy Board or G.S. 90-14(a)(1), (a)(3) through (a)(14) and (c) as determined by the Medical Board; or

(5) the CPP has failed to comply with any of the provisions of this Rule.

Any modification of treatment for financial gain on the part of the Supervising Physician or CPP shall be grounds for denial of Board approval of the CPP Agreement.

(j) Fees:

(1) An application fee of one hundred dollars ($100.00) shall be paid at the time of initial application for approval and each subsequent application for approval to practice as a CPP.

(2) The fee for annual renewal of approval, due at the time of annual renewal pursuant to Paragraph (c) of this Rule, is fifty dollars ($50.00).

(3) No portion of any fee in this Rule is refundable.

History Note: *Authority G.S. 90-8.2; 90-18; 90-18.4; 90-85.3; 90-85.18; 90-85.26A;*
Eff. April 1, 2001;
Amended Eff. July 1, 2016; April 1, 2007; March 1, 2004; October 1, 2001;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

SECTION .3200 – PEER REVIEW AGREEMENTS

21 NCAC 46 .3201 DEFINITIONS

The following definitions apply to this Subchapter:

(1) "Board" means the North Carolina Board of Pharmacy.

(2) "Committee" means the Board of Directors established to function as a supervisory and advisory body to the Program.

(3) "Impairment" means mental illness, chemical dependency, physical illness, and aging problems.

(4) "Program" means program established by agreements between special impaired pharmacist peer review organizations and the Board.

History Note: *Authority G.S. 90-85.6; 90-85.41;*
Eff. April 1, 2001;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .3202 PEER REVIEW AGREEMENTS

Peer review activities shall include investigation, review and evaluation of records, reports, complaints, litigation, and other information about the practices and practice patterns of pharmacists licensed by the Board and pharmacy technicians registered by the Board. Peer review activities shall also include programs for impaired pharmacists and pharmacy technicians. Peer review agreements may cover some or all of these activities, as deemed appropriate by the Board.

History Note: *Authority G.S. 90-85.6; 90-85.41;*
Eff. April 1, 2001;
Amended Eff. March 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .3203 DUE PROCESS

History Note: *Authority G.S. 90-85.6; 90-85.41;*
Eff. April 1, 2001;
Amended Eff. March 1, 2004;
Expired Eff. November 1, 2017 pursuant to G.S. 150B-21.3A.

21 NCAC 46 .3204 RECEIPT AND USE OF INFORMATION OF SUSPECTED IMPAIRMENT

(a) Information concerning suspected impairments may be received by the Program through reports by pharmacists, pharmacy technicians, family members, and others, and through self-referral.
(b) Upon receipt of information of a suspected impairment, the Program shall initiate an investigation.
(c) The Program may conduct routine inquiries regarding suspected impairments.
(d) Pharmacists or pharmacy technicians suspected of impairment may be required to submit to personal interviews before any person authorized by the Program.

History Note: *Authority G.S. 90-85.6; 90-85.41;*
Eff. April 1, 2001;
Amended Eff. March 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .3205 INTERVENTION AND REFERRAL

(a) When, following an investigation, impairment is confirmed, an intervention shall be conducted using techniques designed to assist the pharmacist or pharmacy technician in acknowledging responsibility for dealing with the impairment. The pharmacist or pharmacy technician shall be referred to a treatment source.
(b) Methods and objectives of interventions shall be decided on a case-by case basis.
(c) Interventions shall be arranged and conducted as soon as possible. In cases referred by the Board a representative of the Board may be present.
(d) Treatment sources shall be evaluated before receiving case referrals from the Program.
(e) Intervention outcomes, including treatment contracts that are elements of an intervention, shall be recorded by the Program.

History Note: *Authority G.S. 90-85.6; 90-85.41;*
Eff. April 1, 2001;
Amended Eff. March 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .3206 MONITORING TREATMENT

A treatment source receiving referrals from the Program shall be monitored as to its ability to provide:
(1) medical and non-medical staffing;

(2) treatment; and
(3) post-treatment support.

History Note: *Authority G.S. 90-85.6; 90-85.41;*
Eff. April 1, 2001;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .3207 MONITORING REHABILITATION AND PERFORMANCE

(a) Monitoring requirements for each pharmacist or pharmacy technician shall be designated by the Program. Pharmacists and pharmacy technicians may be tested regularly or randomly, on Program demand.
(b) Treatment sources may be required to submit reports regarding a pharmacist's or pharmacy technician's rehabilitation and performance to the Program.
(c) Impaired pharmacists and pharmacy technicians may be required to submit to periodic personal interviews before any person authorized by the Program.
(d) Case records shall be maintained by the Program.

History Note: *Authority G.S. 90-85.6; 90-85.41;*
Eff. April 1, 2001;
Amended Eff. March 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .3208 MONITORING POST-TREATMENT SUPPORT

(a) Post-treatment support may include family counseling, advocacy and other services and programs deemed appropriate to improve recoveries.
(b) Treatment sources' post-treatment support shall be monitored by the Program on an ongoing basis.
(c) The Program's post-treatment support shall be monitored by the Program on an ongoing basis.

History Note: *Authority G.S. 90-85.6; 90-85.41;*
Eff. April 1, 2001;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .3209 REPORTS OF INDIVIDUAL CASES TO THE BOARD

(a) Upon investigation and review of a pharmacist licensed by the Board or pharmacy technician registered by the Board, the Program shall report immediately to the Board detailed information about any pharmacist or pharmacy technician as required under G.S. 90-85.41(d).
(b) The Program shall submit quarterly a report to the Board on the status of all pharmacists and pharmacy technicians then involved in the Program who have been previously reported by the Board. The Program shall submit monthly to the Board a report on the status of any pharmacist or pharmacy technician previously reported to the Board then in active treatment.

History Note: *Authority G.S. 90-85.6; 90-85.41;*
Eff. April 1, 2001;
Amended Eff. March 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .3210 PERIODIC REPORTING OF STATISTICAL INFORMATION

Statistical information concerning suspected impairments, impairments, self-referrals, post-treatment support and other demographic and substantive information collected through Program operations shall be included in comprehensive statistical reports compiled and annually reported to the Board by the Program.

History Note: *Authority G.S. 90-85.6; 90-85.41;*
Eff. April 1, 2001;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .3211 CONFIDENTIALITY

Any nonpublic information acquired, created, or used in good faith by the Program shall be treated according to G.S. 90-85.41.

History Note: *Authority G.S. 90-85.6; 90-85.41;*
Eff. April 1, 2001;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

SECTION .3300 - REGISTRATION OF A PHARMACY TECHNICIAN

21 NCAC 46 .3301 REGISTRATION

(a) Following initial registration with the Board, registration of a pharmacy technician shall be renewed annually through the Board's electronic renewal process and shall expire on December 31. It shall be unlawful to work as a pharmacy technician more than 60 days after expiration of the registration without renewing the registration. A registration expired for more than 60 days due to non-renewal shall be reinstated only if the applicant meets the requirements of 21 NCAC 46 .1612.
(b) The current registration of a pharmacy technician shall be available for inspection by agents of the Board.
(c) Pharmacy technicians who provide services solely at a free clinic as defined in G.S. 90-85.44 shall register with the Board and complete the training program described in G.S. 90-85.15A, but are exempt from the pharmacy technician registration fee.

History Note: *Authority G.S. 90-85.6; 90-85.15A;*
Eff. April 1, 2003;
Amended Eff. February 1, 2006; February 1, 2005;
Temporary Amendment Eff. March 28, 2006;
Amended Eff. July 1, 2015; July 1, 2006;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

SECTION .3400 – AUTOMATED DISPENSING ON DRUG SUPPLY DEVICES

21 NCAC 46 .3401 DEFINITIONS

For purposes of this Section, the following terms are defined as follows:

(1) "Automated medication system" means a robotic, mechanical, or computerized device that is not used for drug compounding and is designed to:
  (a) Distribute drugs in a licensed health care facility that holds a pharmacy permit; or
  (b) Package drugs for final distribution by a pharmacist.
(2) "Distribution" means the process of providing a drug to an individual authorized to administer drugs and licensed as a health care provider in the state of North Carolina pursuant to an order issued by an authorized prescriber.
(3) "Override medication" means:
  (a) A drug that may be removed from an automated medication system prior to pharmacist review because the Multidisciplinary Committee has determined that the clinical status of the patient would be compromised by delay; or
  (b) A drug determined by the Multidisciplinary Committee to have a low risk of drug allergy, drug interaction, dosing error, or adverse patient outcome, which may be removed from an automated medication system independent of a pharmacist's review of the medication order or clinical status of the patient.
(4) "Physician controlled medication" is a drug ordered, prepared and administered by a physician or under the physician's direct supervision.

History Note: *Authority G.S. 90-85.6; 90-85.32; 90-85.33;*
Eff. April 1, 1999;
Amended Eff. February 1, 2005; August 1, 2002;
Recodified from 21 NCAC 46 .1814 Eff. February 1, 2005;
Amended Eff. December 1, 2013;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .3402 GENERAL REQUIREMENTS FOR THE USE OF AUTOMATED MEDICATION SYSTEMS

(a) The pharmacist-manager shall assure compliance with all requirements of the Pharmacy Practice Act and this Section.

(b) The pharmacist-manager shall be responsible for:

(1) Maintaining a record of each transaction or operation;

(2) Controlling access to the automated medication system;

(3) Maintaining policies and procedures for:

(A) Operating the automated medication system;

(B) Training personnel who use the automated medication system;

(C) Maintaining patient services whenever the automated medication system is not operating; and

(D) Defining a procedure for a pharmacist to grant access to the drugs in the automated medication system or to deny access to the drugs in the automated medication system.

(4) Securing the automated medication system;

(5) Assuring that a patient receives the pharmacy services necessary for appropriate pharmaceutical care;

(6) Assuring that the automated medication system maintains the integrity of the information in the system and protects patient confidentiality;

(7) Establishing a procedure for stocking or restocking the automated medication system; and

(8) Insuring compliance with all requirements for packaging and labeling.

(c) A pharmacist shall perform prospective drug use review and approve each medication order prior to administration of a drug except an override medication or a physician controlled medication.

(d) A pharmacist shall perform retrospective drug use review for an override medication.

(e) The pharmacist-manager shall convene or identify a Multidisciplinary Committee, which is charged with oversight of the automated medication system. The Multidisciplinary Committee shall:

(1) Include the pharmacist-manager or the pharmacist-manager's designee;

(2) Establish the criteria and process for determining which drug qualifies as an override medication; and

(3) Develop policies and procedures regarding the operation of the automated medication system.

(f) A pharmacy utilizing an automated medication system may distribute patient-specific drugs within the health care facility without verifying each individual drug selected or packaged by the system, if:

(1) The initial medication order has been reviewed and approved by a pharmacist; and

(2) The drug is distributed for subsequent administration by a health care professional permitted by North Carolina law to administer drugs.

(g) The pharmacist-manager shall be responsible for establishing a quality assurance program for the automated medication system. The program shall provide for:

(1) Review of override medication utilization;

(2) Investigation of any medication error related to drugs distributed or packaged by the automated medication system;

(3) Review of any discrepancy or transaction reports and identification of patterns of inappropriate use or access of the automated medication system;

(4) Review of the operation of the automated medication system;

(5) Integration of the automated medication system quality assurance program with the overall continuous quality improvement program of the pharmacy; and

(6) Assurance that individuals working with the automated medication system receive appropriate training on operation of the system and procedures for maintaining pharmacy services when the system is not in operation.

(h) The pharmacist-manager shall maintain, for at least three years, the following records related to the automated medication system in a readily retrievable manner:

(1) Transaction records for all non-controlled drugs or devices distributed by the automated medication system;

(2) Transaction records from the automated medication system for all controlled substances dispensed or distributed; and

(3) Any report or analysis generated as part of the quality assurance program required by Paragraph (g) of this Rule.

History Note: *Authority G.S. 90-85.6; 90-85.32; 90-85.33;*
Eff. February 1, 2005;

Amended Eff. December 1, 2013;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .3403 MULTIDISCIPLINARY COMMITTEE FOR DECENTRALIZED AUTOMATED MEDICATION SYSTEMS

History Note: *Authority G.S. 90-85.6; 90-85.32; 90-85.33;*
Eff. February 1, 2005;
Repealed Eff. December 1, 2013.

21 NCAC 46 .3404 STOCKING OR RESTOCKING OF AN AUTOMATED MEDICATION SYSTEM

(a) Responsibility for accurate stocking and restocking of an automated medication system lies with the pharmacist-manager and with any pharmacist tasked with supervising such functions as specified in Subparagraph (b)(2) of this Rule.

(b) The stocking or restocking of an automated medication system, where performed by someone other than a pharmacist, shall follow one of the following procedures to ensure correct drug selection:

(1) A pharmacist shall conduct and document a daily audit of drugs placed or to be placed into an automated medication system by a pharmacy technician, which audit may include random sampling.

(2) A bar code verification, electronic verification, or similar verification process shall be utilized to assure correct selection of drugs placed or to be placed into an automated medication system. The utilization of a bar code, electronic, or similar verification process shall require an initial quality assurance validation, followed by a quarterly quality assurance review by a pharmacist. When a bar code verification, electronic verification, or similar verification process is utilized as specified in this section, stocking and restocking functions may be performed by a pharmacy technician or by a registered nurse trained and authorized by the pharmacist-manager.

(c) The pharmacist performing the quality assurance review shall maintain a record of the quality assurance process that occurred and the pharmacist approval of the drug stocking, restocking or verification process.

(d) Medication Reuse. Any drug that has been removed from the automated medication system shall not be replaced into the system unless:

(1) the drug's purity, packaging, and labeling have been examined according to policies and procedures established by the pharmacist-manager to determine that reuse of the drug is appropriate; or

(2) specific drugs, such as multi-dose vials, have been exempted by the Multidisciplinary Committee.

History Note: *Authority G.S. 90-85.6; 90-85.32; 90-85.33;*
Eff. February 1, 2005;
Amended Eff. December 1, 2013;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.

21 NCAC 46 .3405 CENTRALIZED AUTOMATED MEDICATION SYSTEMS
21 NCAC 46 .3406 QUALITY ASSURANCE PROGRAM
21 NCAC 46 .3407 RECORD KEEPING
21 NCAC 46 .3408 COMPLIANCE

History Note: *Authority G.S. 90-85.6; 90-85.32; 90-85.33;*
Eff. February 1, 2005;
Repealed Eff. December 1, 2013.

SECTION .3500 – CONTROLLED SUBSTANCES REPORTING SYSTEM

21 NCAC 46 .3501 REPORTS FROM THE CONTROLLED SUBSTANCES REPORTING SYSTEM

The Department of Health and Human Services may submit a report to the Board of Pharmacy if it receives information that the Department of Health and Human Services believes provides a basis to investigate whether a pharmacy, pharmacist or technician has dispensed prescriptions for controlled substances in a manner that may violate laws governing the dispensing of controlled substances or the practice of pharmacy.

History Note: *Authority G.S. 90-85.6; 90-85.12; 90-113.74;*

Eff. March 1, 2014;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.