

NCBOP - Pharmacy Rules

Updated as of July 2011

NORTH CAROLINA ADMINISTRATIVE CODE Board of Pharmacy---Pharmacy Rules

Sections .0100 through .1100 have been repealed.

SECTION .0100 - ORGANIZATION OF THE BOARD

SECTION .0200 - GENERAL DEFINITIONS

SECTION .0300 - HOSPITALS: OTHER HEALTH FACILITIES

SECTION .0400 - EXAMINATIONS: ADMISSION REQUIREMENTS

SECTION .0500 - LICENSES AND PERMITS

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

SECTION .0700 - FORMS

SECTION .0800 - ADMINISTRATIVE HEARING PROCEDURES

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

SECTION .1000 - RULEMAKING PROCEDURES

SECTION .1100 - ELECTIONS

Repealed Eff.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.*

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.*

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.*

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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.

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.

SECTION .1300 - GENERAL DEFINITIONS

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| 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

The definitions of various terms used in this Chapter are found in G.S. 90, Article 4A, and as follows:

- (1) Ambulation Assistance Equipment. Devices that aid in walking, excluding canes, crutches, and walkers.
- (2) Approved School or College of Pharmacy. A school or college of pharmacy accredited by the American Council on Pharmaceutical Education, or a foreign school with a professional pharmacy degree program of at least five years approved by the Board.
- (3) Auxiliary Drug Inventory. A secure, segregated, supplementary source for drugs to be used solely for the purpose of providing adequate drug availability when the pharmacy is closed or the pharmacist is unavailable.
- (4) Board. As defined in G.S. 90-85.3(b).

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- (5) Certified technician. A technician who has passed a pharmacy technician certification board exam, or its equivalent, that has been approved by the Board according to the rules in this Chapter.
- (6) Consultant Pharmacist. A licensed pharmacist who, in collaboration with the supervising physician and nurse practitioner or assistant to the physician, develops a retrospective drug utilization review program which:
 - (a) reviews the appropriateness of the choice of medication(s) for the patient and the patient's therapeutic regimen, including choice of medication, dose, frequency, and route of administration;
 - (b) identifies and resolves therapeutic duplication in the patient's medication regimen; and
 - (c) considers patient-specific medication contraindications.The consultant pharmacist holds himself available for consultation in person, by telephone, or by other means of direct communication at all times when drugs are dispensed.
- (7) Diagnostic equipment. Equipment used to record physiological information while a person goes about normal daily living or while asleep in order to document a disease process. Early pregnancy tests (EPTs), thermometers, glucose meters, and cholesterol equipment are not included as diagnostic equipment.
- (8) Drug review or Pharmaceutical care assessment. An onsite review of a patient's or resident's record by a licensed pharmacist that involves interpretation and evaluation of the drug therapy and other pharmaceutical care services to achieve intended medication outcomes and minimize negative effects of drug therapy.
- (9) Duplicate as used in G.S. 90-85.24. Any license, permit, or registration issued or reissued by the Board which is identical to a previously issued license, permit, or registration, including a permit reissued due to a change in pharmacist-manager.
- (10) Emergency Drugs. Those drugs whose prompt use and immediate availability are generally regarded by physicians as essential in the proper treatment of unforeseen adverse changes in a patient's health or well-being.
- (11) Employee. A person who is or would be considered an employee under the North Carolina Workers' Compensation Act. This definition applies to locations both within and outside of this State holding pharmacy or device and medical equipment permits and without regard to the number of persons employed by the permit holder.
- (12) Executive Director. The Secretary-Treasurer and Executive Director of the Board.
- (13) Graduate of an Approved School or College of Pharmacy. A person who has received an undergraduate professional degree in pharmacy from an approved school or college of pharmacy, or a person who has graduated from a foreign professional school of pharmacy and has successfully completed the Foreign Pharmacy Graduate Equivalency Examination offered by the National Association of Boards of Pharmacy and the Test of English as a Foreign Language.
- (14) HMES. Home medical equipment supplier.
- (15) Health Care Facility Pharmacy. A pharmacy maintained in a hospital, clinic, nursing home, rest home, sanitarium, non-federal governmental institution, industrial health facility, or other like health service under the supervision of a pharmacist; or the central area in a hospital, clinic, or other health care facility where drugs are procured, stored, processed, or issued, or where pharmaceutical services are performed.
- (16) Indulgence in the Use of Drugs. The use of narcotic drugs or other drugs affecting the central nervous system or the use of intoxicating beverages to an extent as to deprive the user of reasonable self-control or the ability to exercise such judgment as might reasonably be expected of an average prudent person.
- (17) Internet Pharmacy.
 - (a) A pharmacy that maintains an Internet web site for the purpose of selling or distributing prescription drugs; or
 - (b) A pharmacy that uses the internet, 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 uses such communication or information, in whole or in part, to otherwise 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 an Internet web site for the following purposes only:
 - (i) Mere advertisements that do not attempt to facilitate, directly or through agreement with a third party, an actual transaction involving a prescription drug;
 - (ii) To allow a patient to communicate a request for a refill of a legitimate prescription originally filled by the pharmacy that maintains the Internet web site;
 - (iii) To allow a customer to research drug interactions and clinical pharmacology information; or
 - (iv) To allow a patient to send an electronic mail message to a pharmacist licensed in North Carolina.

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- (18) Limited Service Pharmacy Permit. A pharmacy permit issued by the Board to an applicant that wishes to render in an institutional setting pharmaceutical services not limited to scope and kind but to time and conditions under which such services are rendered.
- (19) Medication Therapy Management Services and Related Functions. Included in the practice of pharmacy as part of monitoring, recording and reporting drug therapy and device usage.
- (20) Medication Administration Record. A record of drugs administered to a patient.
- (21) Medication Order. An order for a prescription drug or other medication or a device for a patient from a person authorized by law to prescribe medications.
- (22) Mobility equipment. Devices that aid a person in self-movement, other than walking, including manual or power wheelchairs and scooters.
- (23) Oxygen and respiratory care equipment. Equipment or devices used to administer oxygen or other legend drugs, maintain viable airways or monitor cardio-respiratory conditions or events, including compressed medical gases; oxygen concentrators; liquid oxygen; nebulizers; compressors; aerosol therapy devices; portable suction machines; nasal continuous positive airway pressure (CPAP) machines; Bi-phasic positive pressure devices (BiPAP); infant monitors, such as apnea monitors and cardio-respiratory monitors; positive and negative pressure mechanical ventilators; and pulse oximeters.
- (24) Patient Medication Profile. A list of all prescribed medications for a patient.
- (25) Pharmacist. Any person within the definition set forth in G.S. 90-85.3(p), including any druggist.
- (26) Pharmacist-Manager. The person who accepts responsibility for the operation of a pharmacy in conformance with all statutes and rules pertinent to the practice of pharmacy and distribution of drugs by signing the permit application, its renewal or addenda thereto.
- (27) Pharmacy. Any place within the definition set forth in G.S. 90-85.3(q), including any apothecary or drugstore.
- (28) Pharmacy Intern. Any person who is registered with the Board under the internship program of the Board to acquire pharmacy experience or enrolled in approved academic internship programs. A pharmacy intern working under a pharmacist preceptor or supervising pharmacist may, while under supervision, perform all acts constituting the practice of pharmacy.
- (29) Place of residence. Any place used as an individual's temporary or permanent home.
- (30) President. The President of the Board.
- (31) Rehabilitation environmental control equipment. Equipment or devices which permit a person with disabilities to control his or her immediate surroundings.
- (32) Rehabilitation Services. Services and equipment required to maintain or improve functional status and general health as prescribed by the physician which are uniquely specified for each individual's lifestyle. The people involved in this process include the patient, caregiver, physician, therapist, rehabilitation equipment supplier and others who impact on the individual's life style and endeavors.
- (33) Signature. A written or electronic signature or computerized identification code.
- (34) Two Years College Work. Attendance at a college accredited by an accrediting agency recognized by the United States Department of Education for two academic years of not less than eight and one-half months each and the completion of work for credit leading to a baccalaureate degree or its equivalent and that would permit the student to advance to the next class.
- (35) Undergraduate Professional Degree in Pharmacy. A B.S. or Pharm. D. degree.
- (36) Vice-President. The Vice-President of the Board.

History Note: Authority G.S. 90-85.3; 90-85.6; 90-85.8; 90-85.13; 90-85.14; 90-85.15; 90-85.21; 90-85.38; 90-85.40; Eff. May 1, 1989;
Amended Eff. February 1, 2007; March 1, 2004; April 1, 1999; May 1, 1997; September 1, 1995;
September 1, 1993; October 1, 1990; January 1, 1990.

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.

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(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.

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.

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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.*

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 periodically reviewed to assure they reflect current practice in the facility. A copy of such procedures shall be available in the pharmacy.

(b) The pharmacist-manager shall be responsible for the safe and effective distribution, control, 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 deviation from this Section, the facility's pharmacy permit is subject to action by the Board. In addition to Rule 21 NCAC 46.2502, the pharmacist-manager shall, at a minimum, be 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; supportive pharmacy personnel are properly directed and supervised;
- (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 proper disposition in a timely manner;
- (8) maintaining records and reports as are required to ensure patient health, safety and welfare. These records and reports shall include, at a minimum:
 - (A) access to medication administration records;
 - (B) reports of suspected adverse drug reactions and medication variances;
 - (C) list of contents of ancillary drug cabinets where allowed and emergency kits/crash carts;
 - (D) the current formulary of drugs where a formulary is required;
 - (E) a biennial controlled substances inventory;
 - (F) alcohol and flammable material reports as required by law when such material is procured by the pharmacy; and
 - (G) such other records and reports as may be required by law and rules of the Board of Pharmacy;
- (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:

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- (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) recurring losses or mishandling of significant quantities of controlled substances shall be immediately reported to the Board and the Drug Enforcement Administration;
- (10) maintaining policies and procedures which require at least monthly inspections of patient care units or other areas of the health care facility where medications are dispensed, administered, or stored. For long-term care facilities and adult care homes, quarterly inspections are permitted, as defined by state licensure regulations. A record of such inspections shall be maintained to verify that:
 - (A) antiseptics, other drugs for external use, and disinfectants are stored separately from internal and injectable medications;
 - (B) drugs requiring special conditions for storage to assure stability are properly stored;
 - (C) all necessary and required security and storage standards are met;
 - (D) outdated or otherwise unusable drugs are identified, their distribution and administration prevented, and such are returned to the pharmacy for proper disposition;
 - (E) the distribution and administration of controlled drugs are adequately documented by pharmacy, nursing, and other involved services or personnel and are in accordance with applicable law;
 - (F) any investigational drugs in use are properly stored, distributed, and controlled;
 - (G) emergency drugs, as approved by the medical staff, are in adequate and proper supply in the pharmacy or other designated areas of the health care facility; and
 - (H) metric-apothecaries' weight and measure conversion tables and charts are available;
- (11) all drugs and devices dispensed by the pharmacy as defined in G.S. 90-85.3(e) which 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.

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 sufficient 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) Compounding and dispensing areas;
- (2) Physically separate parenteral solution additive area when parenteral solutions are compounded as described in Section .2800 - Sterile Parenteral Pharmaceuticals 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, at a minimum, meet basic local building code requirements for the storage of volatile substances and such other laws, ordinances, or regulations that may apply.
- (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.

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 after normal working hours by use of an "on call" pharmacist accessible to the facility during all absences, and an ancillary drug cabinet as described in Rule .1414(g) 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;

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- (2) a nurse trained and authorized by the pharmacist-manager to remove drugs or devices from the pharmacy after hours. Entry into the pharmacy after hours shall occur only if the drug needed is not in the ancillary drug cabinet. 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 cannot be taken from the pharmacy and can 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 suitable record of drugs or devices removed from ancillary drug cabinets or from pharmacy inventory shall be maintained for three years in the health care facility. 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 certain 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 ancillary drug supply 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 an ancillary drug cabinet; 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. August 1, 2000.

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 put in writing 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, at a minimum, shall contain the:
 - (A) patient's name, location and other necessary 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) date the order was written; and
 - (D) 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 shall be entered into a patient medication profile, either manual or automated. The medication profile shall, at a minimum, contain the:
 - (A) patient's name, location and important clinical data 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) Medication orders shall be reviewed and discontinued or suspended, if appropriate, when the patient is transferred to the delivery room, operating room, or is admitted from another facility. A method to protect the patient from indefinite, open-ended drug orders must be provided. The prescriber shall be notified in a timely manner that the order shall be stopped before such action takes place by one or more of the following:

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- (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 drug orders after a predetermined time interval unless rewritten by the prescriber.
- (6) Health care facilities which 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) **DEVICES.** Devices shall be dispensed in accordance with Section .2600 of this Chapter.
- (c) **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, Rule .1413 of this Section shall apply in the absence of a pharmacist.
- (d) **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) Whenever 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 pharmacy, the pharmacist-manager shall develop policies and procedures for preparation and labeling.
- (e) **PARENTERAL MEDICATIONS.** The dispensing of parenteral medications shall be done in accordance with Section .2800 of this Chapter--Sterile Parenteral Pharmaceuticals.
- (f) **PATIENT CARE UNIT MEDICATION INVENTORIES.** This Paragraph does not apply to nursing facilities, assisted living facilities, and adult care homes.
- (1) The pharmacist-manager shall develop an approved drug list for each health care facility location. Non-controlled drugs may be stocked on a health care facility patient care unit in quantities limited to not more than five dosage units per drug when immediate availability is deemed essential to the patient's health and well-being. Drugs shall be stored in a manner that prevents unauthorized access and shall only be administered to a patient of the health care facility pursuant to a medication order.
 - (2) All controlled substances stocked within a health care facility that are not located within the facility's pharmacy or automated dispensing device must be accompanied by a disposition form issued from the pharmacy. This document shall at a minimum contain:
 - (A) the product name, strength, dosage form, and quantity supplied;
 - (B) the date transferred to the patient care unit by the pharmacy;
 - (C) the name of the pharmacy representative supplying, and the patient care unit representative receiving the drug;
 - (D) the date, time, and amount of the drug removed from the patient care unit stock for administration; and
 - (E) the patient name and identification of the person acquiring the product.
 - (3) Exceptions to this Paragraph shall be made for use of automated dispensing devices provided that these devices meet all applicable rules for controlled substances contained therein.
 - (4) When a dose of a controlled substance has been prepared for a patient but not used (i.e., refused, order canceled, or contaminated), it may be destroyed at the patient care unit. The destruction must be witnessed by a health care provider, such as a pharmacist, registered nurse, or licensed practical nurse. The pharmacist-manager shall ensure that details of the event, along with the identification of the two who effected and witnessed the destruction, are documented. If such record is separate from the disposition form, it shall be maintained uniformly with the corresponding disposition form.
- (g) **ANCILLARY DRUG CABINET INVENTORIES.** (This Paragraph does not apply to nursing facilities, assisted living facilities, and adult care homes.) Drugs that are routinely prescribed by the medical staff in a health care facility shall be maintained in quantities limited to not more than five dosage units per drug as a supplementary inventory for use only when the pharmacy is closed. The pharmacist-manager shall, in connection with the appropriate committee of the health care facility, develop listings of those drugs to be included in such inventories. The pharmacist-manager shall, at a minimum, assure that:
- (1) access to such drug inventories is by locked cabinet(s) or other enclosure(s) constructed and secured to deny access to unauthorized persons;
 - (2) only authorized personnel, as indicated by written policies and procedures, shall obtain access to the drug inventories;
 - (3) only pre-packaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements. Drugs shall be properly labeled, with drug name, strength, lot number and expiration date. Whenever access to such inventory is gained, a copy of the record of withdrawal and a copy of the written order for new drug orders shall be provided to the pharmacy. The record of withdrawal shall contain the following:

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- (A) the date of removal of the drug;
 - (B) the name, strength, dosage form, and quantity of drug removed;
 - (C) the name of the patient for whom the drug was ordered;
 - (D) the name or identification code of the authorized personnel removing the drug from inventory;
- (4) all drugs are reviewed no less often than quarterly to ensure their purity, potency, and integrity; and
- (5) written policies and procedures are established to implement the requirements of this Rule.
- (h) **AUTOMATED DISPENSING OR DRUG SUPPLY DEVICES.** Automated Dispensing or Drug Supply Devices such as but not limited to Pyxis machines may be utilized in health care facility pharmacies and where a pharmacy permit exists in accordance with 21 NCAC 46 .1814.
- (i) **EMERGENCY KITS.** (This Paragraph does not apply to adult care homes or assisted living facilities) Drugs and devices may be provided in emergency kits for use by authorized personnel provided the pharmacist-manager, in conjunction with the medical staff of the health care facility, develop and implement written policies and procedures to ensure compliance with the following provisions:
- (1) the pharmacist-manager, or designee, and the medical staff of the health care facility jointly determine the drugs and devices, by identity and quantity, to be included in the kit. Drugs and devices included in the kit shall be limited to those for emergency use only and are not to be used for any other purpose.
 - (2) the emergency kit contains those drugs and devices which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent prolonged discomfort or risk of harm to patients;
 - (3) the emergency kit shall be stored in a secure, readily available location under the supervision of the nursing staff and sealed with a non-reusable, removable seal to prevent unauthorized access, and to ensure a proper environment for preservation of the drugs and devices within them. Policies and procedures shall be established to ensure the integrity of the kit at all times;
 - (4) the exterior of the emergency kit shall be labeled so as to clearly and unmistakably indicate that it is an emergency drug kit and is for use in emergencies only. In addition, a listing of the drugs and devices contained therein, including name, strength, and quantity of each drug or device shall be attached. Each emergency kit shall be inspected by a pharmacist or his designee every 30 days (90 days for long-term care facilities) to check for expiration dates and the integrity of the seal;
 - (5) all drugs and devices contained within the emergency kit shall be labeled, if applicable, with, at a minimum, the name, strength, lot number, manufacturer, and expiration date;
 - (6) drugs and devices shall be removed from the emergency kit for administration to a patient only pursuant to a valid physician's order, by personnel authorized by the facility;
 - (7) whenever an emergency kit is opened, the pharmacy shall be notified. The pharmacist-manager or designee shall re-stock, re-seal, and return the kit to the unit within a reasonable length of time in order to prevent risk of harm to patients. The emergency drug kits shall be checked by an authorized person in accordance with written policies and procedures of the health care facility. In the event the kit is opened in an unauthorized manner, the pharmacy and other personnel designated by the pharmacist-manager of the facility shall be notified; and
 - (8) Emergency drugs that are controlled substances must be stored in compliance with 10A NCAC 26E .0408.
- (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 shall permit the identification of the responsible pharmacists and pharmacy technicians. Readily retrievable records of accountability shall be maintained for at least 30 days. At a minimum, 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) periodically assessing the quality of pharmacy procedures for preparation and release of drugs and devices for replenishment of floor stock, ancillary drug supplies, 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 such medication error. Documentation shall include pertinent 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

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21 NCAC 46 .2502(k) RESPONSIBILITY OF PHARMACIST-MANAGER), 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, but are not limited to the following:
 - (A) Invoices or other such documents verifying the ordering and receipt of controlled substances;
 - (B) Perpetual inventories of controlled substances transferred to patient care units and other sites as allowed by this Rule (i.e., automated dispensing devices, emergency kits, etc.). These inventories shall record the transfer date; location transferred to; the identity of the drug; strength, dosage form, and quantity transferred; transferring pharmacist's name;
 - (C) Disposition records required by Paragraph (f)(4) of this Rule;
 - (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 shall be maintained 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 (via CRT display and hard-copy printout) of original medication order information and dispensing history consistent with criteria cited in 21 CFR .1306.
- (6) With the exception of Subparagraph (j)(1) 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. February 1, 2005; April 1, 2003; April 1, 1999; August 1, 1998

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 only be dispensed 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 appropriate 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) Such drugs shall be prepackaged in safety closure containers and shall be appropriately pre-labeled by the pharmacist to comply with 21 NCAC 46.1414(i)(5) of this Chapter. Prior to dispensing, the following information shall be placed on the label:
 - (A) name, address, and telephone number of the health care facility pharmacy;
 - (B) dispensing date;
 - (C) full name of patient;
 - (D) 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) 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. Such record shall, at a minimum, contain the following:
 - (A) date dispensed;

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- (B) patient's name;
 - (C) physician's name; and
 - (D) name of drug dispensed, strength, dosage form, quantity dispensed, and dose.
- (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 regulations governing the dispensing of medications including patient counseling as defined in 21 NCAC 46 .2504 Patient Counseling.

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.

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.

21 NCAC 46 .1417 REMOTE MEDICATION ORDER PROCESSING SERVICES

- (a) Purpose. The purpose of this Section is to set out requirements for health care facility pharmacies providing remote medication order processing services and facilities contracting with remote medication order processing services.
- (b) Definition. Medication order processing does not include the dispensing of a prescription drug but includes any of the following:
- (1) receiving, interpreting, or clarifying medication orders;
 - (2) data entry and transferring of medication order information;
 - (3) performing drug regimen review;
 - (4) interpreting clinical data;
 - (5) performing therapeutic interventions; and
 - (6) providing drug information concerning medication orders or drugs.
- (c) Outsourcing. A pharmacy may outsource medication order processing to another pharmacy provided the pharmacies have the same owner or the pharmacy has entered into a written contract or agreement with an outsourcing company that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations. The pharmacy providing the remote processing of medication orders must notify the Board of Pharmacy prior to providing such services.
- (d) Training. A pharmacy providing remote medication order processing must ensure that all pharmacists providing such services have been trained on each pharmacy's policies and procedures relating to medication order processing. The training of each pharmacist shall be documented by the pharmacist-manager to ensure competency and to ensure that performance is at least at the same level of performance as pharmacists in the outsourcing pharmacy. Such training shall include policies on drug and food allergy documentation, abbreviations, administration times, automatic stop orders, substitution, and formulary compliance. The pharmacies shall jointly develop a procedure to communicate changes in the formulary and changes in policies and procedures related to medication order processing.
- (e) Access. The pharmacies must share common electronic files or have appropriate technology to allow secure access to the pharmacy's information system and to provide the remote pharmacy with access to the information necessary or required to process a medication order.
- (f) Communication. The pharmacies must jointly define the procedures for resolving problems detected during the medication order review and communicating these problems to the prescriber and the nursing staff providing direct care.
- (g) Recordkeeping. A pharmacy using remote order entry processing services is responsible for maintaining records of all orders entered into their information system including orders entered from a remote location. The system shall have the ability to audit the activities of the individuals remotely processing medication orders.

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(h) Licensure. All pharmacies providing remote order processing services must be permitted by the Board. An out-of-state pharmacy providing remote order processing services must be registered with the Board as an out-of-state pharmacy. All pharmacists located in this State or employed by an out-of-state pharmacy providing remote order processing services to health care facilities in this State, shall be licensed by the Board.

(i) Policy and Procedure Manual. All pharmacies involved in remote order processing shall maintain a policy and procedure manual. Each remote pharmacy is required to maintain those portions of the policy and procedure manual that relate to that pharmacy's operations. The manual shall:

- (1) outline the responsibilities of each of the pharmacies;
- (2) include a list of the name, address, telephone numbers, and all license/registration numbers of the pharmacies involved in remote order processing; and
- (3) include policies and procedures for:
 - (A) protecting the confidentiality and integrity of patient information;
 - (B) maintaining appropriate records to identify the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist who performed any processing;
 - (C) complying with federal and state laws and regulations;
 - (D) operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems;
 - (E) annually reviewing the written policies and procedures and documenting such review; and
 - (F) annually reviewing the competencies of pharmacists providing the remote order review service.

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.

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

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- (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.

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: Legislative Objection Lodged Eff. March 29, 1983;
Authority G.S. 90-85.6; 90-85.15; 90-85.24;
Eff. April 1, 1983;
Curative Eff. April 1, 1983;
Amended Eff. July 1, 2005; May 1, 1989.

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.

21 NCAC 46 .1503 EXPERIENCE IN PHARMACY

- (a) An applicant for license must show that he has received 1500 hours of practical experience under the supervision of a licensed pharmacist which has been acquired after the satisfactory completion of two years of college work. The Board shall accept hours of experience certified by the school from which the applicant has graduated.
- (b) All practical pharmacy experience to be acceptable must be acquired under the general conditions approved by the Board as follows:
 - (1) All practical pharmacy experience must be validated through registration in the internship program administered by the Board.
 - (2) Persons working under the supervision of registered pharmacists and expecting to qualify for the registered pharmacist examination must notify the Board within five days of the beginning and the ending of such employment.
 - (3) 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.
 - (4) 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 that purpose.

(c) The pharmacist intern, or student, and the pharmacist preceptor, or supervising pharmacist, 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 period of experience from counting toward the minimum requirements. A

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pharmacist preceptor who causes or permits a pharmacist intern to violate the Board's rules or the laws governing the practice of pharmacy and the distribution of drugs forfeits his right to supervise such experience for a period of time determined by 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 preceptor without the approval by the Board.

(d) The Board may accept training in pharmacy gained in another state pursuant to internship registration in this or another state if the Board is satisfied that such training is equivalent.

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.

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: Legislative Objection Lodged Eff. March 29, 1983;
Authority G.S. 90-85.15;
Eff. April 1, 1983;
Curative Eff. April 1, 1983;
Amended Eff. May 1, 1989.

21 NCAC 46 .1505 EXAMINATION

(a) The applicant shall pass the following examinations:

- (1) a national examination;
- (2) a jurisprudence examination; and
- (3) a practical examination which includes an error and omission section.

(b) For the purpose of grading or rating, the answers, which shall be legible, shall be valued by marks or points based on their importance, as determined by the judgment of the examiners.

(c) In order to pass, a score of 75 or more is required on each examination. Candidates who obtain a score of 75 or more on each examination are deemed to have passed the respective examination provided that the candidate obtains a passing score on the remaining examinations within the next following two calendar years. If the examination is taken outside of North Carolina, the examination score shall be properly transferred to North Carolina. A candidate who fails to pass all three examinations in the two calendar year period must retake and pass all three examinations within a two calendar year period.

(d) At the time of the examination, the Board may designate certain questions which, if missed, shall require the candidate to obtain continuing education. The continuing education required will be specified by the Board and must be obtained by the candidate prior to issuance of a pharmacist license.

History Note: Authority G.S. 90-85.15; 90-85.16;
Eff. April 1, 1983;
Amended Eff. April 1, 2004; April 1, 2003; July 1, 1996; December 31, 1985.

21 NCAC 46 .1506 RULES OF EXAMINATION CONDUCT

Candidates must not communicate in any way with another candidate, or give, receive, or use any information concerning the examination, except as specifically directed by the examiner. Any candidate who fails to observe this Rule shall be disqualified for the remainder of the examination and shall forfeit the right to have graded any examination he might have taken thus far. Candidates taking the examination must follow the Instructions given for each examination. Incorrect spelling, grammar, or illegible handwriting may affect the final rating. Time allotted for completion of each division of the examination shall be announced at the time of the examination.

History Note: Authority G.S. 90-85.6; 90-85.15; 90-85.16;
Eff. April 1, 1983;
Amended Eff. May 1, 1989.

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

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*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. The pharmacy's reference library shall include a medical dictionary and current editions of reference books on drug interactions, clinical pharmacology, USP Dispensing Information or its equivalent, and if IV admixture services are provided, a reference on Parenteral Incompatibilities.
- (4) 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.
- (5) 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 as a Verified Internet Pharmacy Practice Site (VIPPS);
- (2) The Internet pharmacy has certified the percentage of its annual business conducted via the Internet on a form required 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.

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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;
Eff. April 1, 1983;
Amended Eff. 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.

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.

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.

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;

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Eff. May 1, 1989;

Amended Eff. June 1, 2004; April 1, 2001; August 1, 1998; May 1, 1997; September 1, 1995.

21 NCAC 46 .1605 CHARGE FOR VERIFICATION FOR REINSTATEMENT

The Board shall charge persons requesting written verification for reinstatement of a pharmacy license or permit or a device and medical equipment permit a fee of twenty-five dollars (\$25.00) per verification.

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.

21 NCAC 46 .1606 REQUIREMENT OF PERSONAL APPEARANCE

Prior to issuance of any original permit or device and medical equipment permit, the following persons must appear personally at the Board office on the first Monday of the month, the Monday before the monthly Board meeting, or such other time as scheduled with the Board's staff:

- (1) the pharmacist-manager for the applicant pharmacy; and
- (2) the person in charge of the facility applying for the device and medical equipment permit.

History Note: Authority G.S. 90-18.1; 90-18.2; 90-85.3(a),(r); 90-85.6; 90-85.21; 90-85.22;

Eff. April 1, 1994;

Amended Eff. April 1, 2003; April 1, 1999; September 1, 1995.

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 into this State.

(b) Such pharmacies shall:

- (1) Maintain, in readily retrievable form, records of prescription drugs dispensed to North Carolina residents;
- (2) 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;
- (3) 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 affixed to each container of dispensed drugs;
- (4) Comply with all USP and FDA requirements regarding the storage, packaging, and shipping of prescription medications;
- (5) Develop policies governing:
 - (A) normal delivery protocols and times;
 - (B) the procedure to be followed if the patient's medication 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 an acute illness, which shall include a procedure for delivery of the medication 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 medication at the earliest possible time; and
 - (D) the procedure to be followed when the out-of-state pharmacy is advised that the patient's medication has not been received within the normal delivery time and that the patient is out of medication and requires interim dosage until mail prescription drugs become available;
- (6) Disclose the location, names, and titles, of all principal corporate officers, if incorporated, and if unincorporated, partners, or owners of the pharmacy. Disclose the names and license numbers of all pharmacists dispensing prescription legend drugs to an ultimate user in this State, the names and, if available, license or registration numbers of all supportive personnel employed by the out-of-state pharmacy who assist such pharmacists in such dispensing. A report containing this information shall be made on an annual basis and within 30 days of each change of any principal office, pharmacist-manager of any location dispensing prescription legend drugs to an ultimate user in this State, principal corporate officer if incorporated, and if unincorporated, partner or owner of the pharmacy. A new registration shall be required for a change of ownership of an established pharmacy to a successor business entity which results in a change in the controlling interest in the pharmacy;
- (7) 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. Such evidence shall consist of one of the following:

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- (A) a copy of the current license, permit, or registration certificate issued by the regulatory or licensing agency of the state in which the pharmacy is located; or
 - (B) a letter from the regulatory or licensing agency of the state in which the pharmacy is located certifying the pharmacy's compliance with the pharmacy laws of that state;
- (8) Designate a resident agent in North Carolina for service of process. Any such out-of-state pharmacy that does not so designate a resident agent shall be deemed to have appointed the Secretary of State of the State of North Carolina to be its true and lawful attorney upon whom process may be served. All legal process in any action or proceeding against such pharmacy arising from shipping, mailing or delivering prescription drugs in North Carolina shall be served on the resident agent. In addition, a copy of such service of process shall be mailed to the out-of-state pharmacy by certified mail, return receipt requested, at the address of the out-of-state pharmacy as designated on the registration form filed with the Board. Any out-of-state pharmacy which does not register in this State, shall be deemed to have consented to service of process on the Secretary of State as sufficient service.
- (c) The facilities and records of an out-of-state pharmacy shall be subject to inspection by the Board; provided however, the Board may accept in lieu thereof satisfactory inspection reports by the licensing entity of the state in which the pharmacy is located.
- (d) An out-of-state pharmacy shall comply with the statutes and regulations of the state in which the pharmacy is located.
- (e) Any person who ships, mails, or delivers prescription drugs to North Carolina residents from more than one out-of-state pharmacy shall register each pharmacy separately.
- (f) Prior to original registration, a pharmacist who is an authorized representative of the pharmacy's owner must appear personally at the Board office on the first Monday of the month, the Monday before the monthly Board meeting, or such other time as scheduled with the Board's staff. Such authorized pharmacist may represent all pharmacies having the same ownership.
- (g) An out-of-state pharmacy shall report to the Board information that reasonably suggests that there is a probability that a prescription drug or device dispensed from such out-of state pharmacy has caused or contributed to the death of any patient. The report shall be filed in writing on a form provided by the Board within 14 days of the pharmacy becoming aware of the death. The Board may not disclose the identity of any person or entity making the report, except when it is necessary to protect life or health of any person. No such report in possession of the Board shall be discoverable or admissible into evidence or otherwise used in any civil action involving private parties, except as otherwise required by law.
- (h) The Board may, in accordance with Chapter 150B of the General Statutes, issue a letter of reprimand or suspend, restrict, revoke, or refuse to grant or renew registration to an out-of-state pharmacy if such pharmacy has:
- (1) made false representations or withheld material information in connection with obtaining registration;
 - (2) been found guilty of or plead guilty or nolo contendere to any felony in connection with the practice of pharmacy or the distribution of drugs;
 - (3) made false representations in connection with the practice of pharmacy that endanger or are likely to endanger the health or safety of the public, or that defraud any person;
 - (4) failed to comply with this Rule;
 - (5) been the subject of a negligence complaint resulting from the dispensing of prescription drugs to a resident of North Carolina and based on an investigation of such complaint been found to be negligent:
 - (A) by the Board of Pharmacy of the state in which the pharmacy is located;
 - (B) by the North Carolina Board of Pharmacy if the Board of Pharmacy of the state where the pharmacy is located failed to initiate an investigation of such complaint within 45 days after referral of the complaint from the North Carolina Board of Pharmacy; or
 - (C) by the North Carolina Board of Pharmacy if the Board of Pharmacy of the state where the pharmacy is located initiates an investigation of such complaint within 45 days, but later advises the North Carolina Board that it will not make a determination of negligence or that it has made no determination of the issue of negligence within one year after referral of the complaint and has discontinued any active investigation or proceeding for such determination. In any disciplinary proceeding based on negligence, the standard of practice shall be that applicable in the state in which the pharmacy is located. In disciplinary proceedings pursuant to Part (h)(5)(A) of this Rule, the Board shall adopt the findings of negligence by the Board of Pharmacy of the state in which the pharmacy is located as part of the Board's final decision without producing its own evidence of negligence.
- (i) An out-of-state pharmacy shall notify the Board within five days of receipt of any order or decision by a Board of Pharmacy imposing disciplinary action on the pharmacy. Notwithstanding the provisions of Paragraph (h) of this Rule, if the permit or registration in the state where the pharmacy is located is suspended or revoked, then the pharmacy's registration in North Carolina will be immediately suspended or revoked for the same period of time.
- (j) An out-of-state pharmacy registration shall expire on December 31 of each year.
- (k) 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 registration and for annual renewal of each registration.

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History Note: Authority G.S. 90-85.6; 90-85.21A; 90-85.26; 90-85.28; 90-85.29; 90-85.30; 90-85.32;
Eff. July 1, 1994;
Amended Eff. March 1, 2006.

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

21 NCAC 46 .1609 PERMIT RENEWAL

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

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History Note: Authority G.S. 90-85.6; 90-85.21;
Eff. September 1, 1995.

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-1331A; 90-85.19;
Eff. September 1, 1995.

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

(a) Any person, firm or corporation submitting to the Board a check which is subsequently returned to the Board because of insufficient funds or because there is no account open at the bank shall be charged a fee of twenty-five dollars (\$25.00) for processing the check.

(b) Until such time as the payor of the returned check pays the amount of the check and pays the prescribed fee, the payor shall not be eligible to take an examination, review an examination, obtain a license or permit or have his license or permit renewed.

(c) Any license or permit which has been issued based on the payment of a check which is subsequently returned to the Board for reasons stated in Paragraph (a) of this Rule shall be declared invalid until such time as the payor pays the amount of the check and pays the prescribed fee.

(d) Payment to the Board of the amount of the returned check and the prescribed fee shall be made in the form of cash, a cashier's check, or money order.

(e) All examination, license and permit, and license and permit renewal applications provided by the Board shall contain information in a conspicuous place thereon advising the applicant of the applicable fee for returned checks.

History Note: Authority G.S. 25-3-506;
Eff. September 1, 1995;
Amended Eff. February 1, 2006.

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.

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

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- who holds a Clinical Pharmacist Practitioner credential or who is a pharmacist vaccinator.
- (2) "Eligible registrant" means a pharmacy technician, dispensing physician, 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. Code 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 fee 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(d), 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; 90-85.17; 90-85.21(b); 90-85.24; 90-85.26A; 93B-15;
Eff. April 1, 2010.

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.

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) The pharmacist shall prepare a plan to ensure that there are adequate amounts of each of the drugs dispensed by a nurse practitioner or physician assistant, and that such drugs are properly stored and packaged.
- (d) All drugs dispensed by a nurse practitioner or physician assistant must be dispensed from a place holding a current pharmacy permit from the Board as required by G.S. 90-85.21.
- (e) The consulting pharmacist shall be available for consultation in person, by telephone, or other means of direct communication at all times when drugs are dispensed.

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(f) All drugs dispensed by the nurse practitioner or physician assistant shall be prepackaged in safety closure containers and shall be appropriately prelabeled (including necessary auxiliary labels) by the pharmacist with all information required by law except the name of the patient and the directions for use. The name of the patient and directions for use of the drugs shall be placed on the label by the nurse practitioner or physician assistant at the time it is delivered to the patient or his agent.

History Note: Authority G.S. 90-18.1; 90-18.2; 90-85.6;
Eff. April 1, 1983;
Amended Eff. April 1, 1999; May 1, 1997; May 1, 1989.

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

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

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

History Note: Authority G.S. 90-18.1; 90-18.2; 90-85.6;
Eff. April 1, 1999.

SECTION .1800 - PRESCRIPTIONS

21 NCAC 46 .1801 RIGHT TO REFUSE A PRESCRIPTION

(a) A pharmacist or device and medical equipment dispenser may refuse to fill or refill a prescription order, if, in his professional judgment, it would be harmful to the recipient, is not in the recipient's best interest or if there is a question as to its validity.

(b) A pharmacist shall not fill or refill a prescription order if the pharmacist actually knows or reasonably should know that the order was issued without a physical examination of the patient and in the absence of a prior prescriber-patient relationship, unless:

- (1) the prescription order was issued for the patient by a psychiatrist;
- (2) the prescription order was issued for the patient after discussion of the patient status with a treating psychologist, therapist, or physician;
- (3) the prescription order was ordered by a physician for flu vaccinations for groups of patients or members of the public;
- (4) the prescription order was for prophylactic purposes, such as the ordering of antibiotics by a pediatrician for members of a child's family when the child has a positive strep test;
- (5) the prescription order was an emergency order for medication related to pregnancy prevention; or
- (6) the prescription order was an order for medications to be taken by groups traveling to foreign countries.

History Note: Authority G.S. 90-85.6; 90-85.32;
Eff. April 1, 1983;
Amended Eff. February 1, 2007; March 1, 2004; April 1, 2003; September 1, 1995.

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).

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(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.*

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.*

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.*

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.*

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:

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- (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.

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

A drug product which is manufactured and sold by a manufacturer as a generic drug product shall be considered a generic drug product, though subsequently repackaged and given a brand name.

History Note: Authority G.S. 90-85.6(a); 90-85.32;
Eff. December 1, 1991.

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;

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Eff. September 1, 1993;
Amended Eff. April 1, 1999; September 1, 1995.

21 NCAC 46 .1810 COMPOUNDING

In accordance with G.S. 90-85.3(c) and (r), and 90-85.6(a), the Board has primary jurisdiction over compounding occurring in locations holding a pharmacy permit, and such compounding shall comply with the following:

- (1) based on the existence of a practitioner-pharmacist-patient relationship and the presentation of a valid prescription, or in anticipation of prescription orders based on established prescribing patterns, a pharmacist may compound a drug product for an individual patient. A pharmacist also may compound a drug product prior to receiving a valid prescription based on a history of receiving valid prescriptions generated within an established practitioner-pharmacist-patient relationship. Compounded drug products shall not be offered to other entities for resale; however, practitioners may obtain compounded drug products to administer to patients within the scope of their professional practice;
- (2) the pharmacist is responsible for all aspects of compounding; however, unlicensed personnel working under the supervision of the pharmacist may assist in compounding;
- (3) drug substances used for compounding shall be USP or NF grade, or if unavailable, AR, CP, ACS, or FCC grade substances may be used. If none of the foregoing grades are available, then the pharmacist must establish the purity and safety of the ingredient prior to its use. Manufactured drug products used for ingredients must be labeled with a batch control number and a future expiration date;
- (4) equipment and utensils used for compounding shall not be reactive, additive or absorptive so that the safety, identity, strength, quality, and purity of the compounded drug product will not be adversely affected. All compounding equipment and utensils shall be cleaned and sanitized prior to use. A compounding pharmacy shall have written procedures and formulas for the compounding of drug products;
- (5) any excess compounded drug product retained by the pharmacy shall be labeled with a complete list of ingredients or reference to such information, the preparation date, and an expiration date based upon the pharmacist's professional judgment. The excess compounded drug product shall be stored under conditions to preserve its strength, quality and purity;
- (6) with the exception of the simple reconstitution of drug products, the pharmacy shall maintain a log showing the name or initials of the person who compounded a drug product and the name or initials of the pharmacist who checked the compounded drug product;
- (7) with the exception of the simple reconstitution of drug products, the pharmacy shall maintain a recordkeeping system from which the date of purchase, supplier, manufacturer, and lot number or other identifier of each ingredient can be determined for each compounded drug product dispensed; provided however, that health care facility pharmacies may comply with this requirement by maintaining records of lot numbers only. All pharmacy records resulting from compounding, including the compounding log, shall be readily retrievable and maintained in the pharmacy for a period of three years;
- (8) in addition to the requirements of this Section, the compounding of radiopharmaceutical drug products shall comply with Section .2700 of this Chapter;
- (9) in addition to the requirements of this Section, the compounding of sterile parenteral drug products shall comply with Section .2800 of this Chapter.

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

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.

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;*

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Eff. April 1, 1997.

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.*

21 NCAC 46 .1814 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 maintaining patient care unit medication inventories or for a patient profile dispensing system, provided the utilization of such 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, at a minimum, shall assure that:

- (1) only authorized personnel, as indicated by written policies and procedures, may obtain access to the drug inventories;
- (2) all drugs therein are reviewed no less than monthly;
- (3) a system of accountability must exist for all drugs contained therein; the purity, potency, and integrity of the drugs shall be preserved;
- (4) the device provides records required by this Section and other applicable laws and rules;
- (5) requirements for controlled substances security are met; and
- (6) 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 Rule 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.

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History Note: Authority G.S. 90-85.6; 90-85.32; 90-85.33;
Eff. April 1, 1999;
Amended Eff. August 1, 2002.

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.

21 NCAC 46 .1816 PROCEDURES FOR CENTRALIZED PROCESSING OF PRESCRIPTION ORDERS

(a) A pharmacy permitted by the Board may process a request for the filling or refilling of a prescription order received by a pharmacy within this State, provided:

- (1) The pharmacy that is to fill or refill the prescription either has a contract with the pharmacy which received the prescription or has the same owner as the other pharmacy.
- (2) The prescription container:
 - (A) is clearly labeled with all information required by Federal and State laws and regulations; and
 - (B) clearly shows the name and address of the pharmacy refilling the prescription and the name and address of the pharmacy which receives the refilled prescription for dispensing to the patient.
- (3) The patient is provided with written information, either on the prescription label or with the prescription container, that describes which pharmacy to contact if the patient has any questions about the prescription or medication.
- (4) Both pharmacies maintain complete and accurate records of the prescription, including:
 - (A) the name of the pharmacist who fill or refills the prescription;
 - (B) the name of the pharmacy filling or refilling the prescription; and
 - (C) the name of the pharmacy that received the fill or refill request.
- (5) The pharmacy that fills or refills the prescription and the pharmacy that receives the prescription for dispensing to the patient share a common electronic file.
- (6) The originating pharmacy is responsible for compliance with the requirements of Federal and State laws and regulations regarding recordkeeping and patient counseling.

(b) Nothing in this Rule shall be construed as barring a pharmacy from also filling new prescriptions presented by a patient or a patient's agent or transmitted to it by a prescriber.

History Note: Authority G.S. 90-85.6; 90-85.32;
Eff. August 1, 2000.

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;

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- (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.

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.

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.

21 NCAC 46 .1902 APPLICATION FOR PHARMACIST'S LICENSE

The form for application for a pharmacist's license is "Application for Examination and Registered Pharmacist Certificate." All applicants for admission to the examination for licensure as a pharmacist shall submit this form. In addition to the normal questions of identification, this form requests responses on education, experience, prior activity, proof of qualifications and character.

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

21 NCAC 46 .1903 APPLICATION FOR PHARMACY PERMIT

The form for application for pharmacy permit is entitled "Application for Registration and Permit to Conduct a Pharmacy." All persons who desire to conduct a pharmacy shall complete this form for original and renewal applications. Information requested includes facility name and address, type of organization (i.e., proprietorship, corporation, non-profit hospital, government), ownership, supervised personnel, pharmacist personnel, and hours of service.

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

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.

21 NCAC 46 .1905 REPLACEMENT OF CERTIFICATES

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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.

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.

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.

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.

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.

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

The form certifying graduation is entitled "Certificate of Graduation from College or School of Pharmacy" and must be completed by all candidates for licensure. This form provides for listing of dates of attendance and date of graduation, and is to be completed by a responsible official of the school or college.

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

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

The form for application for registration as a dispensing physician is entitled "Application for Registration with the Pharmacy Board as a Dispensing Physician", and appears in G.S. 90-85.21(b). All applicants for registration as a dispensing physician shall complete this form for original and renewal applications. Information requested includes name and address of dispensing physician, physician's North Carolina license number, whether the physician is currently practicing in a professional association registered with the North Carolina Board of Medical Examiners, the name and registration number of the professional corporation, if applicable, and a certification that the information given is correct and complete.

History Note: Authority G.S. 90-85.6; 90-85.21;
Eff. February 1, 1991.

21 NCAC 46 .1913 APPLICATION FOR DEVICE DISPENSING PERMIT

The form for application for a permit to dispense devices is entitled "Application for Permit to Dispense Devices". All applicants for a "Device Dispensing Permit" shall complete this form for original and renewal applications. Information requested includes name and address of place dispensing devices, name and address of person in charge of permit, history of person in charge of permit, examples of prescription devices dispensed from location during the last year, and two attestations by persons not employed or supervised by device dispenser.

History Note: Authority G.S. 90-85.6; 90-85.22;
Eff. February 1, 1991.

SECTION .2000 - ADMINISTRATIVE PROVISIONS

21 NCAC 46 .2001 RIGHT TO HEARING

(a) When the Board acts or proposes to act, other than in rulemaking or declaratory ruling proceedings, in a manner which will affect the rights, duties, or privileges of a specific, identifiable person, such person has the right to an administrative hearing. When the Board proposes to act in such a manner, it shall give such person notice of the right to a hearing by mailing by certified mail to that person at the last known address of that person a notice of the proposed action and a notice of a right to a hearing.

(b) Prior to issuing the notice called for in Paragraph (a) of this Rule, and with the consent of the party or parties, the Board may attempt to settle disputes through the informal procedures set out in Rule .2008(a) of this Section.

History Note: Authority G.S. 90-85.6; 150B-11; 150B-22; 150B-38; 150B-41;
Eff. April 1, 1983;
Amended Eff. October 1, 1990; May 1, 1989; July 1, 1988; March 1, 1987.

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) Any time an individual believes that individual's rights, duties, or privileges have been affected substantially by the Board's administrative action, but has not received notice of a right to an administrative hearing, that individual may file a formal request for a hearing.

(b) Before an individual may file a request, that individual is encouraged to exhaust all reasonable efforts to resolve the issue informally with the Board.

(c) Subsequent to such informal action, if still dissatisfied, the individual may submit a request to the Board's office, with the request bearing the notation: REQUEST FOR ADMINISTRATIVE HEARING. The request shall contain the following information:

- (1) name and address of the petitioner;
- (2) a concise statement of the action taken by the Board which is challenged;
- (3) a concise statement of the way in which the petitioner has been aggrieved; and
- (4) a clear and specific statement of request for a hearing.

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(d) A request for administrative hearing must be submitted to the Board's office within 60 days of receipt of notice of the action taken by the Board which is challenged. The request will be acknowledged promptly and, if deemed appropriate by the Board in accordance with 21 NCAC 46 .2005, a hearing shall be scheduled.

History Note: Authority G.S. 90-85.6; 150B-38;
Eff. September 1, 1988;
Amended Eff. August 1, 2002.

21 NCAC 46 .2005 GRANTING OR DENYING HEARING REQUEST

(a) The Board will grant a request for a hearing if it determines that the party requesting the hearing is a "person aggrieved" within the meaning of G.S. 150B-2(6).

(b) The denial of request for a hearing will be issued immediately upon decision, and in no case later than 60 days after the submission of the request. Such denial shall contain a statement of the reasons leading the Board to deny the request.

(c) Approval of a request for a hearing will be signified by the issuing of a notice as required by G.S. 150B-38(b) and explained in Rule .2006 of this Section.

History Note: Authority G.S. 90-85.6; 150B-11; 150B-38;
Eff. July 1, 1988.

21 NCAC 46 .2006 NOTICE OF HEARING

(a) The Board shall give the party or parties in a contested case a notice of hearing not less than 15 days before the hearing. Said notice shall contain the following information, in addition to the items specified in G.S. 150B-38(b):

- (1) the name, position, address and telephone number of a person at the offices of the Board to contact for further information or discussion;
- (2) the date, time, and place for a pre-hearing conference, if any; and
- (3) any other information deemed relevant to informing the parties as to the procedure of the hearing.

(b) If the Board determines that the public health, safety or welfare requires such action, it may issue an order summarily suspending a license or permit. Upon service of the order, the licensee or permit holder to whom the order is directed shall immediately cease the practice of pharmacy or cease the dispensing of devices and medical equipment in North Carolina. The Board shall promptly give notice of hearing pursuant to G.S. 150B-38 following service of the order. The suspension shall remain in effect pending issuance by the Board of a final agency decision pursuant to G.S. 150B-42.

History Note: Authority G.S. 90-85.6; 150B-3(c); 150B-11; 150B-38;
Eff. July 1, 1988;
Amended Eff. September 1, 1995; May 1, 1989.

21 NCAC 46 .2007 WHO SHALL HEAR CONTESTED CASES

(a) All administrative hearings shall be conducted by the Board, a panel consisting of a majority of the members of the Board, or an administrative law judge designated to hear the case pursuant to G.S. 150B-40(e).

(b) Matters involving device and medical equipment permit holders shall be initially heard by a device and medical equipment subcommittee. The subcommittee shall be elected pursuant to Section .2100 of this Chapter. Prior to issuing a notice of hearing, the subcommittee and the party or parties may agree to follow the informal procedures set out in Rule .2008 of this Section.

(c) After hearing the matter, the device and medical equipment subcommittee shall propose a recommended decision to the Board. Sanctions shall be consistent with G.S. 90-85.38. If the Board accepts the recommended decision, it shall

constitute a final agency decision for the right to judicial review. If the Board rejects the recommended decision, the Board may propose an alternative decision or schedule the matter for a formal hearing before the Board.

History Note: Authority G.S. 90-85.6; 150B-11; 150B-38; 150B-40;
Eff. July 1, 1988;
Amended Eff. September 1, 1995.

21 NCAC 46 .2008 INFORMAL PROCEDURES

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(a) Prior to issuing a notice of hearing, the Board or the device and medical equipment subcommittee and the party or parties may agree to conduct a conference in which a member of the Board or the device and medical equipment subcommittee and the party or parties meet to consider the possibility of disposing of the dispute without a hearing or any other matter as may aid in the prompt disposition of the dispute. If such a conference is held, the Board, or the device and medical equipment subcommittee, 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 to resolve by consent; or
- (3) Scheduling, with appropriate notice, for contested case hearing.

All recommendations of dismissal must be approved by the Board. Any consent order proposed may dispose of the dispute or set forth such matters as were agreed to between the parties that may expedite the hearing. All matters contained in the consent order must be agreed to by the party or parties and approved by the Board at its next regular meeting. The Board member or member of the device and medical equipment subcommittee 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 21 NCAC 46 .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) After issuance of a notice of hearing, the Board or the device and medical equipment subcommittee and the party or parties may agree in advance to simplify the hearing by: decreasing the number of issues to be contested at the hearing; accepting the validity of certain proposed evidence; accepting the findings in some other case with relevance to the case at hand; or agreeing to such other matters as may expedite the hearing.

History Note: Authority G.S. 90-85.6; 150B-41;
Eff. July 1, 1988;
Amended Eff. April 1, 2001; September 1, 1995; October 1, 1990; May 1, 1989.

21 NCAC 46 .2009 PETITION FOR INTERVENTION

(a) A person desiring to intervene in a contested case must file a written petition with the Board's office. The request should bear the notation: PETITION TO INTERVENE IN THE CASE OF (Name of case).

(b) The petition must include the following information:

- (1) the name and address of petitioner;
- (2) the business or occupation of petitioner, where relevant;
- (3) a full identification of the hearing in which petitioner is seeking to intervene;
- (4) the statutory or non-statutory grounds for intervention;
- (5) any claim or defense in respect of which intervention is sought; and
- (6) a summary of the arguments or evidence petitioner seeks to present.

(c) The moving party must serve copies of the petition on all parties to the case.

(d) If the Board determines to allow intervention, notice of that decision will be issued promptly to all parties, and to the petitioner. In cases of discretionary intervention, such notification will include a statement of any limitations of time, subject matter, evidence or whatever else is deemed necessary which are imposed on the intervenor.

(e) If the Board's decision is to deny intervention, the petitioner will be notified promptly. Such notice will be in writing, identifying the reasons for the denial, and will be issued to the petitioner and all parties.

History Note: Authority G.S. 90-85.6; 150B-11; 150B-38;
Eff. July 1, 1988;
Amended Eff. May 1, 1989.

21 NCAC 46 .2010 TYPES OF INTERVENTION

(a) Intervention of Right. A petition to intervene as of right, as provided in the North Carolina Rules of Civil Procedure, Rule 24, will be granted if the petitioner meets the criteria of that rule and their petition is timely.

(b) Permissive Intervention. A petition to intervene permissibly as provided in the North Carolina Rules of Civil Procedure, Rule 24, will be granted if the petitioner meets the criteria of that rule and the Board determines that:

- (1) There is sufficient legal or factual similarity between the petitioner's claimed rights, privileges, or duties and those of the parties to the hearing; and
- (2) Permitting intervention by the petitioner as a party would aid the purpose of the hearing.

(c) Discretionary Intervention. The Board may allow discretionary intervention with whatever limits and restrictions are deemed appropriate.

History Note: Authority G.S. 90-85.6; 150B-11; 150B-38;
Eff. July 1, 1988;
Amended Eff. May 1, 1989.

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21 NCAC 46 .2011 DISQUALIFICATION OF BOARD MEMBERS

- (a) Self-disqualification. If for any reason a Board member determines that personal bias or other factors renders that Board member unable to hear a contested case and perform all duties in an impartial manner, that Board member shall voluntarily decline to participate in the hearing or decision.
- (b) Petition for disqualification. If for any reason any party in a contested case believes that a Board member is personally biased or otherwise unable to hear a contested case and perform all duties in an impartial manner, the party may file a sworn, notarized affidavit with the Board. The title of such affidavit should bear the notation: AFFIDAVIT OF DISQUALIFICATION OF BOARD MEMBER IN THE CASE OF (Name of case).
- (c) Contents of affidavit. The affidavit must state all facts the party deems to be relevant to the disqualification of the Board member.
- (d) Timeliness of affidavit.
- (1) An affidavit of disqualification will be considered timely if filed ten days before commencement of the hearing. Any other affidavit will be considered timely provided it is filed at the first opportunity after the party becomes aware of facts which give rise to a reasonable belief that a Board member may be disqualified under this Rule.
 - (2) Where an affidavit for disqualification is filed less than ten days before or during the course of a hearing, the hearing shall continue with the challenged Board member sitting. Petitioner shall have the opportunity to present evidence supporting his petition, and the petition and any evidence relative thereto presented at the hearing shall be made a part of the record. The Board, before rendering its decision, shall decide whether the evidence justifies disqualification. In the event of disqualification, the disqualified member will not participate in further deliberation or decision of the case.
- (e) Procedure for determining disqualification.
- (1) The Board will appoint a Board member to investigate the allegations of the affidavit.
 - (2) The investigator will report findings to the Board and make recommendations.
 - (3) The Board shall decide whether to disqualify the challenged individual.
 - (4) The person whose disqualification is to be determined will not participate in the decision but may be called upon to furnish information to the other members of the Board.
 - (5) When a Board member is disqualified prior to the commencement of the hearing or after the hearing has begun, such hearing will continue with the remaining members sitting provided that the remaining members still constitute a majority of the Board.
 - (6) 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-11; 150B-38; 150B-40;
Eff. July 1, 1988;
Amended Eff. May 1, 1989.*

21 NCAC 46 .2012 RESERVED FOR FUTURE CODIFICATION

21 NCAC 46 .2013 SUBPOENAS

- (a) Requests for subpoenas for the attendance and testimony of witnesses or for the production of documents, either at a hearing or for the purposes of discovery, shall be made in writing to the Board and shall identify any document sought with specificity, and shall include the full name and home or business address of all persons to be subpoenaed and, if known, the date, time, and place for responding to the subpoena. The Board shall issue the requested subpoenas within three days of receipt of the request.
- (b) Subpoenas shall contain: the caption of the case; the name and address of the person subpoenaed; the date, hour and location of the hearing in which the witness is commanded to appear; a particularized description of the books, papers, records or objects the witness is directed to bring with him to the hearing, if any; the identity of the party on whose application the subpoena was issued; the date of issue; the signature of one of the members of the Board or the Board's executive director; and a "return of service." The "return of service" form as filled out, shows the name and capacity of the person serving the subpoena, the date on which the subpoena was delivered to the person directed to make service, the date on which service was made, the person on whom service was made, the manner in which service was made, and the signature of the person making service.

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- (c) Subpoenas shall be served by the sheriff of the county in which the person subpoenaed resides, when the party requesting such subpoena prepays the sheriff's service fee. The subpoena shall be issued in duplicate, with a "return of service" form attached to each copy. A person serving the subpoena shall fill out the "return of service" form for each copy and properly return one copy of the subpoena, with the attached "return of service" form completed, to the Board.
- (d) Except as otherwise stated in a particular subpoena, any person receiving a subpoena from the Board may object thereto by filing a written objection to the subpoena with the Board's office.
- (e) Such objection shall include a concise, but complete, statement of reasons why the subpoena should be revoked or modified. These reasons may include lack of relevancy of the evidence sought, or any other reason sufficient in law for holding the subpoena invalid, such as that the evidence is privileged, that appearance or production would be so disruptive as to be unreasonable in light of the significance of the evidence sought, or other undue hardship.
- (f) Any such objection to a subpoena must be served on the party who requested the subpoena simultaneously with the filing of the objection with the Board.
- (g) The party who requested the subpoena, in such time as may be granted by the Board, may file a written response to the objection. The written response shall be served by the requesting party on the objecting witness simultaneously with filing the response with the Board.
- (h) After receipt of the objection and response thereto, if any, the Board shall issue a notice to the party who requested the subpoena and the party challenging the subpoena, and may notify any other party or parties of an open hearing, to be scheduled as soon as practicable, at which time evidence and testimony may be presented, limited to the narrow questions raised by the objection and response.
- (i) Promptly after the close of such hearing, a majority of the Board members with voting authority, or an administrative law judge assigned to the case pursuant to G.S. 150B-40(e), will rule on the challenge and issue a written decision. A copy of the decision will be issued to all parties and made a part of the record.

History Note: Authority G.S. 90-85.6; 150B-11; 150B-38; 150B-39;
Eff. September 1, 1988.

21 NCAC 46 .2014 WITNESSES

Any party may be a witness and may present witnesses on the party's behalf at the hearing. All oral testimony at the hearing shall be under oath or affirmation and shall be recorded. At the request of a party or upon the Board's own motion, 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-11; 150B-38; 150B-40;
Eff. July 1, 1988.

21 NCAC 46 .2015 FINAL DECISION

In all cases heard by the Board, the Board will issue its decision within 60 days after its next regularly scheduled meeting following the close of the hearing. This decision will be the prerequisite "final agency decision" for the right to judicial review.

History Note: Authority G.S. 90-85.6; 150B-11; 150B-38; 150B-42;
Eff. July 1, 1988;
Amended Eff. May 1, 1989.

21 NCAC 46 .2016 PROPOSALS FOR DECISIONS

- (a) When an administrative law judge conducts a hearing pursuant to G.S. 150B-40(e), a "proposal for decision" shall be rendered within 45 days of the hearing pursuant to the rules of the Office of Administrative Hearings, 26 NCAC 3 .0026. Any party may file written exceptions to this "proposal for decision" and submit their own proposed findings of fact and conclusions of law. The exceptions and alternative proposals must be filed within ten days after the party has received the "proposal for decision" as drafted by the administrative law judge.
- (b) Any exceptions to the procedure during the hearing, the handling of the hearing by the administrative law judge, rulings on evidence, or any other matter must be written and refer specifically to pages of the record or otherwise precisely identify the occurrence to which exception is taken. The exceptions must be filed with the Board within ten days of the receipt of the proposal for decision. The written exceptions should bear the notation: EXCEPTIONS TO THE PROCEEDINGS IN THE CASE OF (Name of case).
- (c) Any party may present oral argument to the Board upon request. The request must be included with the written exceptions.

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(d) Upon receipt of request for further oral argument, notice will be issued promptly to all parties designating the time and place for such oral argument.

(e) Giving due consideration to the proposal for decision and the exceptions and arguments of the parties, the Board may adopt the proposal for decision or may modify it as the Board deems necessary. The decision rendered will be a part of the record and a copy thereof given to all parties. The decision as adopted or modified becomes the "final agency decision" for the right to judicial review. Said decision will be rendered by the Board within 60 days of the next regularly scheduled meeting following the oral arguments, if any. If there are no oral arguments presented, the decision will be rendered within 60 days of the next regularly scheduled Board meeting following filing of the written exceptions.

History Note: Authority G.S. 90-85.6; 150B-11; 150B-38; 150B-40;
Eff. July 1, 1988;
Amended Eff. May 1, 1989.

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

(a) Eligible voters for Board members shall be the pharmacists licensed in North Carolina and residing in North Carolina on March 15 immediately prior to the election.

(b) Eligible voters for the device and medical equipment subcommittee shall be all device and medical equipment permit holders in North Carolina and residing in North Carolina on March 15 immediately prior to the election.

History Note: Authority G.S. 90-85.7; 90-85.22;
Eff. April 1, 1983;
Amended Eff. September 1, 1995; May 1, 1989.

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.

21 NCAC 46 .2104 COMMITTEE ON NOMINATIONS

The Board may appoint an advisory committee on nominations in January of each year. Members of this committee shall submit at least two names of eligible candidates for each position to be filled on the Board and on the device and medical equipment subcommittee by March 1 for the next election.

History Note: Authority G.S. 90-85.7;

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Eff. April 1, 1983;
Amended Eff. July 1, 1996; May 1, 1989.

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, such document to be filed in the Board office or postmarked before March 10 for the next election. Nominations shall be closed on March 15th.

History Note: Legislative Objection Lodged Eff. March 29, 1983;
Authority G.S. 90-85.7;
Eff. April 1, 1983;
Curative Eff. April 1, 1983;
Amended Eff. May 1, 1989.

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.

21 NCAC 46 .2107 BALLOTS: CASTING AND COUNTING

(a) The Board shall provide a ballot to all eligible voters in April of each year that there is an election for Board position(s). The Board shall employ the following method for balloting:

- (1) The Board shall provide access to an electronic ballot to all eligible voters; and
- (2) A paper ballot shall be mailed, with return envelope, to any eligible voter who makes a written request for a paper ballot in lieu of access to an electronic ballot and whose request is actually received by the Board on or before April 20.

(b) A description of a nominee's qualifications shall be accessible to all eligible voters casting their ballots electronically. The same description of the nominee's qualifications shall accompany each paper ballot sent pursuant to Subparagraph (a)(2) of this Rule.

(c) On or before May 15, all ballots shall be cast electronically, physically delivered to the Board office, or postmarked, if the ballot is sent by U. S. mail.

(d) Ballots received shall be counted and certified by the Board of Pharmacy at the next regularly scheduled Board meeting following an election. The Board of Pharmacy shall determine the validity of any challenged ballot, and electronic and/or mechanical devices may be used in compiling election results. No person running for election or re-election may participate in the counting and certification of ballots for the election or re-election involving that person.

(e) 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. January 1, 2009; April 1, 2003.

21 NCAC 46 .2108 DETERMINATION OF ELECTION RESULTS

The determination of election results shall be in accordance with G.S. 163-111, which is adopted herein by reference and includes subsequent amendments and editions. A copy of G.S. 163-111 is available for inspection at the Board office and may be obtained from the Board office for a cost of 25 cents (\$.25) per page.

History Note: Authority G.S. 90-85.7;
Eff. March 1, 1991;
Amended Eff. December 1, 2001.

21 NCAC 46 .2109 DEVICE AND MEDICAL EQUIPMENT COMMITTEE REPRESENTATIVES

(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 appointed by the President of the Board.

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(b) All device and medical equipment permit holders are eligible to vote for one representative in each category specified in Subparagraphs (a)(1)-(3) of this Rule. The representative must practice in the particular area for which he or she is nominated, but need not practice exclusively in that area.

(c) The representatives specified in Subparagraphs (a)(1)-(3) of this Rule shall be elected or appointed to terms of five years, and may not serve more than two consecutive five-year terms. The committee may establish a staggered schedule for the elections. In case of death, resignation or removal from the committee, the remaining members of the committee shall elect a representative who meets the criteria for the position.

History Note: Authority G.S. 90-85.6; 90-85.22;
Eff. September 1, 1995;
Amended Eff. April 1, 2003.

SECTION .2200 - CONTINUING EDUCATION

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

(a) As a condition of license renewal, a pharmacist shall accumulate 15 hours of continuing education annually.

(b) Eight 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 on-line continuing education course may satisfy this contact-hour requirement provided that the live two-way communication standard is met.

(c) A pharmacist who accumulates more than the required 15 hours of continuing education in a single year may carry forward up to five surplus hours to be applied to the following year's continuing education requirements.

(d) A pharmacist shall preserve all continuing education records for three years.

(e) Upon license renewal, the pharmacist shall report continuing education hours on a form approved and provided by the Board. 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.

(f) All continuing education shall be obtained through accredited continuing education courses. The Board shall approve continuing education courses as accredited if they provide education on matters that will maintain or increase the participant's professional competence and proficiency as a pharmacist.

(g) Continuing education shall not serve as a barrier to reciprocity; however all licensees by reciprocity must observe the continuing education standards specified in (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.

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.

21 NCAC 46 .2302 RECORDS OF DISPENSING

(a) Records of dispensing for original and refill prescriptions are to be made and kept by pharmacies for three years and shall include, but are not limited to:

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- (1) quantity dispensed, if quantity of refill is different than quantity of original;
 - (2) date of dispensing;
 - (3) serial number (or equivalent in an institution);
 - (4) the identification of the pharmacist responsible for dispensing;
 - (5) records of refills to date;
 - (6) documentation of satisfaction of state requirements for drug selection.
- (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. May 1, 1989.

21 NCAC 46 .2303 RECORDS OF PRESCRIPTION FILLING AND REFILLING

In a pharmacy with a manual system, the dispensing pharmacist shall indicate by date and initial the filling or refilling of a prescription on the document. In a pharmacy with a computer or data system, a designation of the dispensing pharmacist accompanied by the daily signature of the pharmacist filling or refilling each prescription is required as noted in Rule .2304(3)(a) or (3)(b). 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. May 1, 1989.

21 NCAC 46 .2304 AUTOMATED DATA PROCESSING SYSTEMS

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

- (1) The system shall have the capability of producing sight-readable documents of all original and refilled prescription information. The term "sight-readable" means that a regulatory agent shall be able to examine the record and read the information. In the case of administrative proceedings before the Board, records must be provided in a readable paper printout form.
- (2) Such information shall include, but not be limited to 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 must provide documentation of the fact that prescription information entered into the computer is correct. In documenting this information, the pharmacist shall have the option of either:
 - (a) providing a printout of each day's prescription information. That printout shall be dated and the individual pharmacist shall verify that the information indicated is correct and sign the printout in the same manner as a check or legal document (e.g. J.H. Smith, or John H. Smith). Such printout must be maintained three years from the date of last dispensing; or
 - (b) maintaining a log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement each day attesting to the fact that the prescription information entered into the computer that day has been reviewed and is correct as shown. Such a book or file must be maintained at the pharmacy employing such a system for a period of three years after the date of last dispensing.
- (4) Documentation in Paragraph (3) of this Rule must be provided in the pharmacy within 72 hours of date of dispensing.
- (5) An auxiliary recordkeeping system shall be 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 Paragraph shall preclude 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) A pharmacy shall make 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 such supplier is terminated for any reason. A pharmacy shall assure continuity in the maintenance of records.
- (7) A current version of drug interactions software shall be used and policies and procedures shall be established to address overriding the interactions prompt.

History Note: Authority G.S. 90-85.6(a); 90-85.26; 90-85.32; 90-107;

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Eff. December 31, 1985;
Amended Eff. April 1, 1999; May 1, 1989.

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.

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;
- (2) No drugs or devices may be dispensed except at health department clinics;
- (3) The health department shall secure the services of a pharmacist-manager who shall be responsible for developing and supervising a system of control and accountability of all drugs dispensed from the health department;
- (4) Only the general categories of drugs or devices listed in Rule .2403 may be dispensed by a health department registered nurse;
- (5) All drugs or devices dispensed pursuant to G.S. 90-85.34A and these rules shall be packaged in suitable safety-closure containers, where appropriate, and shall be properly labelled (including necessary auxiliary labels) so as to provide information necessary for use and all other information required by state and federal law;
- (6) A suitable and perpetual record of drugs or devices dispensed shall be maintained in the health department. 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;
- (7) The duties of the pharmacist-manager set out in Paragraphs (1) through (6) in this Rule may be delegated to a pharmacist licensed by the Board. The pharmacist-manager shall remain personally responsible for compliance with all statutes, rules, and regulations governing the practice of pharmacy and dispensing of drugs.

History Note: Authority G.S. 90-85.6; 90-85.34A;
Eff. March 1, 1987;
Amended Eff. May 1, 1989.

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.

21 NCAC 46 .2403 DRUGS AND DEVICES TO BE DISPENSED

(a) Pursuant to the provisions of G.S. 90-85.34A(a)(3), prescription drugs and devices included in the following general categories may be dispensed by registered nurses in local health department clinics when prescribed for the indicated conditions:

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- (1) Anti-tuberculosis drugs, as defined by the latest edition of Drug Facts and Comparisons, as published by Facts and Comparison Div., J.B. Lippincott Co., or as recommended by the Tuberculosis Control Branch of the North Carolina Division of Health Services, when used for the treatment and control of tuberculosis;
 - (2) Anti-infective agents used in the control of sexually-transmitted diseases as recommended by the United States Centers for Disease Control;
 - (3) Natural or synthetic hormones and contraceptive devices when used for the prevention of pregnancy;
 - (4) Topical preparations for the treatment of lice, scabies, impetigo, diaper rash, vaginitis, and related skin conditions; and
 - (5) Vitamin and mineral supplements.
- (b) Regardless of the provisions set out in this Rule, no drug defined as a controlled substance by the United States Controlled Substances Act, 21 U.S. Code 801 through 904, or regulations enacted pursuant to that Act, 21 CFR 1300 through 1308, or by the North Carolina Controlled Substances Act, G.S. 90-86 through 90-113.8, may be dispensed by registered nurses pursuant to G.S. 90-85.34A.

History Note: Authority G.S. 90-85.6; 90-85.34A;
Eff. March 1, 1987;
Amended Eff. July 1, 1996; May 1, 1989.

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.

21 NCAC 46.2502 RESPONSIBILITIES OF PHARMACIST-MANAGER

- (a) The pharmacist-manager shall assure that prescription legend drugs and controlled substances are safe and secure within the pharmacy.
- (b) The pharmacist-manager employed or otherwise engaged to supply pharmaceutical services may have a flexible schedule of attendance but shall be present for at least one-half the hours the pharmacy is open or 32 hours a week, whichever is less. A pharmacist employee not meeting this requirement may serve as pharmacist-manager of the permit holder temporarily for a period not to exceed 90 days from the departure date of the previous pharmacist-manager, if the pharmacist employee is present at least 20 hours per week in the pharmacy.
- (c) Whenever a change of ownership or change of pharmacist-manager occurs, the successor pharmacist-manager shall complete an inventory of all controlled substances in the pharmacy within 10 days. A written record of such inventory, signed and dated by the successor pharmacist-manager, shall be maintained in the pharmacy with other controlled substances records for a period of three years.
- (d) The pharmacist-manager shall develop and implement a system of inventory record-keeping and control which will enable that pharmacist-manager to detect any shortage or discrepancy in the inventories of controlled substances at that pharmacy at the earliest practicable time.
- (e) The pharmacist-manager shall maintain authority and control over any and all keys to the pharmacy and shall be responsible for the security of the pharmacy. A pharmacy shall be secured to prohibit unauthorized entry if no pharmacist will be present in the pharmacy for a period of 90 minutes or more.
- (f) These duties are in addition to the specific duties of pharmacist-managers at institutional pharmacies and pharmacies in health departments as set forth in the Rules in this Chapter.
- (g) A person shall not serve as pharmacist-manager at more than one pharmacy at any one time except for limited service pharmacies.
- (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

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inform the public of such transfer by posted notice at the pharmacy for 15 days after the closing date, if possible.

Controlled substance records shall be retained for the period of time required by law.

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

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

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

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

(m) The Board shall not disclose the identity of a pharmacist-manager who makes a report under Paragraph (l) of this Rule, except as required by law. No report made under Paragraph (l) of this Rule shall be released except as required by law.

(n) In any Board proceeding, the Board shall consider compliance with Paragraph (l) of this Rule as a mitigating factor and noncompliance with Paragraph (l) of this Rule as an aggravating factor.

(o) The pharmacist-manager shall ensure that all starter doses of medication supplied to doctors' offices from the pharmacy are accompanied by written materials advising the patient that such doses of medication may be supplied by any pharmacy. Starter doses shall be limited to a 24 hour dose supply per patient.

History Note: Authority G.S. 90-85.6; 90-85.21; 90-85.25; 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.

21 NCAC 46 .2503 RESEARCH PARTICIPATION

Pharmacists are encouraged to participate in research efforts, including protocol dosing, precision and time of drug administration, obtaining informed consent and other activities connected with investigational drug studies.

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

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

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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.

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.

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History Note: Authority G.S. 90-85.3; 90-85.6;
Eff. September 1, 1995.

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.

21 NCAC 46 .2507 ADMINISTRATION OF VACCINES BY PHARMACISTS

(a) Purpose. The purpose of this Rule is to provide standards for pharmacists engaged in the administration of influenza, pneumococcal and zoster vaccines as authorized in G.S. 90-85.3(r) of the North Carolina Pharmacy Practice Act.

(b) Definitions. The following words and terms, when used in this Rule, shall have the following meanings, unless the context indicates otherwise.

- (1) "ACPE" means Accreditation Council for Pharmacy Education.
- (2) "Administer" means the direct application of a drug to the body of a patient by injection, inhalation, ingestion, or other means by:
 - (A) a pharmacist, an authorized agent under his/her supervision, or other person authorized by law; or
 - (B) the patient at the direction of a physician or pharmacist.
- (3) "Antibody" means a protein in the blood that is produced in response to stimulation by a specific antigen. Antibodies help destroy the antigen that produced them. Antibodies against an antigen usually equate to immunity to that antigen.
- (4) "Antigen" means a substance recognized by the body as being foreign; it results in the production of specific antibodies directed against it.
- (5) "Board" means the North Carolina Board of Pharmacy.
- (6) "Confidential record" means any health-related record that contains information that identifies an individual and that is maintained by a pharmacy or pharmacist such as a patient medication record, prescription drug order, or medication order.
- (7) "Immunization" means the act of inducing antibody formation, thus leading to immunity.
- (8) "Medical Practice Act" means G.S. 90-1, et seq.
- (9) "Physician" means a currently licensed M.D. or D.O. with the North Carolina Medical Board who is responsible for the on-going, continuous supervision of the pharmacist pursuant to written protocols between the pharmacist and the physician.
- (10) "Vaccination" means the act of administering any antigen in order to induce immunity; is not synonymous with immunization since vaccination does not imply success.
- (11) "Vaccine" means a specially prepared antigen, which upon administration to a person may result in immunity.
- (12) Written Protocol-A physician's written order, standing medical order, or other order or protocol. A written protocol must be prepared, signed and dated by the physician and pharmacist and contain the following:
 - (A) the name of the individual physician authorized to prescribe drugs and responsible for authorizing the written protocol;
 - (B) the name of the individual pharmacist authorized to administer vaccines;
 - (C) the immunizations or vaccinations that may be administered by the pharmacist;
 - (D) procedures to follow, including any drugs required by the pharmacist for treatment of the patient, in the event of an emergency or severe adverse reaction following vaccine administration;
 - (E) the reporting requirements by the pharmacist to the physician issuing the written protocol, including content and time frame;
 - (F) locations at which the pharmacist may administer immunizations or vaccinations; and
 - (G) the requirement for annual review of the protocols by the physician and pharmacist.

(c) Policies and Procedures.

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- (1) Pharmacists must follow a written protocol as specified in Subparagraph (b)(12) of this Rule for administration of influenza, pneumococcal and zoster vaccines and the treatment of severe adverse events following administration.
 - (2) The pharmacist administering vaccines must maintain written policies and procedures for handling and disposal of used or contaminated equipment and supplies.
 - (3) The pharmacist or pharmacist's agent must give the appropriate, most current vaccine information regarding the purpose, risks, benefits, and contraindications of the vaccine to the patient or legal representative with each dose of vaccine. The pharmacist must ensure that the patient or legal representative is available and has read, or has had read to him or her, the information provided and has had his or her questions answered prior to administering the vaccine.
 - (4) The pharmacist must report adverse events to the primary care provider as identified by the patient.
 - (5) The pharmacist shall not administer vaccines to patients under 18 years of age.
[Pursuant to S.L.2011-315, Section 3, signed into law by Governor Perdue on June 27, 2011: "A pharmacist licensed under Article 4A of Chapter 90 who may administer vaccines under 21 NCAC 46 .2507 and 21 NCAC 32U .0101 shall be granted the authority to administer influenza vaccine to patients aged 14 years and older pursuant to 21 NCAC 46 .2507 and 21 NCAC 32U .0101."]
 - (6) The pharmacist shall not administer the pneumococcal or zoster vaccines to a patient unless the pharmacist first consults with the patient's primary care provider. The pharmacist shall document in the patient's profile the primary care provider's order to administer the pneumococcal or zoster vaccines. In the event the patient does not have a primary care provider, the pharmacist shall not administer the pneumococcal or zoster vaccines to the patient.
 - (7) The pharmacist shall report all vaccines administered to the patient's primary care provider and report all vaccines administered to all entities as required by law, including any State registries which may be implemented in the future.
- (d) Pharmacist requirements. Pharmacists who enter into a written protocol with a physician to administer vaccines shall:
- (1) hold a current provider level cardiopulmonary resuscitation (CPR) certification issued by the American Heart Association or the American Red Cross or equivalent;
 - (2) successfully complete a certificate program in the administration of vaccines accredited by the Centers for Disease Control, the ACPE or a similar health authority or professional body approved by the Board;
 - (3) maintain documentation of:
 - (A) completion of the initial course specified in Subparagraph (2) of this Paragraph;
 - (B) three hours of continuing education every two years beginning January 1, 2006, which are designed to maintain competency in the disease states, drugs, and administration of vaccines;
 - (C) current certification specified in Subparagraph (1) of this Paragraph;
 - (D) original written physician protocol;
 - (E) annual review and revision of original written protocol with physician;
 - (F) any problems or complications reported; and
 - (G) items specified in Paragraph (g) of this Rule.
- (e) Supervising Physician responsibilities. Pharmacists who administer vaccines shall enter into a written protocol with a supervising physician who agrees to meet the following requirements:
- (1) be responsible for the formulation or approval and periodic review of the physician's order, standing medical order, standing delegation order, or other order or written protocol and periodically review the order or protocol and the services provided to a patient under the order or protocol;
 - (2) be accessible to the pharmacist administering the vaccines or be available through direct telecommunication for consultation, assistance, direction, and provide back-up coverage;
 - (3) review written protocol with pharmacist at least annually and revise if necessary; and
 - (4) receive a periodic status report on the patient, including any problem or complication encountered.
- (f) Drugs. The following requirements pertain to drugs administered by a pharmacist:
- (1) Drugs administered by a 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 immunization or vaccination; or
 - (B) a 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) Pharmacists while engaged in the administration of vaccines under written protocol, may 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 reactions; and
 - (4) After administering vaccines at a location other than a pharmacy, the pharmacist shall return all unused prescription medications to the pharmacy or physician responsible for the drugs.
- (g) Record Keeping and Reporting.

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- (1) A pharmacist who administers any vaccine shall maintain the following information, readily retrievable, in the pharmacy records 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 administering pharmacist.
 - (2) A pharmacist who administers vaccines shall document annual review with physician of written protocol in the records of the pharmacy that is in possession of the vaccines administered.
- (h) Confidentiality.
- (1) The pharmacist shall comply with the privacy provisions of the federal Health Insurance Portability and Accountability Act of 1996 and any rules adopted pursuant to this act.
 - (2) The pharmacist shall comply with any other confidentiality provisions of federal or state laws.

History Note: Authority G.S. 90-85.3; 90-85.6;
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.

21 NCAC 46 .2508 RESERVED FOR FUTURE CODIFICATION

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.

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.

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.

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);

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Eff. April 1, 2007.

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

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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.

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(11) 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), (11), (r); 90-85.6; 90-85.22;
Eff. October 1, 1990;
Amended Eff. March 1, 2006; March 1, 2004; October 1, 1995.

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.

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

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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), (11), (r); 90-85.6; 90-85.22;
Eff. October 1, 1990;
Amended Eff. September 1, 1995.

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),(11),(r); 90-85.6; 90-85.22;
Eff. October 1, 1990;
Amended Eff. April 1, 1999; September 1, 1995.

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.

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), (11), (r); 90-85.6; 90-85.22;
Eff. October 1, 1990;
Amended Eff. September 1, 1995.

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.

21 NCAC 46 .2608 DISPENSING OF MEDICAL OXYGEN

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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),(11),(r); 90-85.6; 90-85.22; Eff. September 1, 1995.

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),(11),(r); 90-85.6; 90-85.22; Eff. September 1, 1995; Amended Eff. April 1, 1999; April 1, 1997.

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:

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- (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),(ll),(r); 90-85.6; 90-85.22;
Eff. September 1, 1995.

21 NCAC 46 .2611 MEDICAL EQUIPMENT

- (a) Medical equipment suppliers shall:

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- (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)(11)(r); 90-85.6; 90-85.22;
Eff. May 1, 1997;
Amended Eff. April 1, 1999; August 1, 1998.

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- (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.
- (c) Device and medical equipment storage sites shall be subject to inspection by the Board.

History Note: Authority G.S. 90-85.6; 90-85.22; 90-85.32;
Eff. March 1, 2004;
Amended Eff. February 1, 2007.

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.

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.

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,

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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.

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.

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.

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History Note: Authority G.S. 90-85.6; 90-85.34;
Eff. October 1, 1990;
Amended Eff. February 1, 2005.

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.

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.

SECTION .2800 - STERILE PHARMACEUTICALS

21 NCAC 46 .2801 SCOPE AND PURPOSE

The purpose of this Section is to provide standards for the preparation, labeling, and distribution of sterile products by licensed pharmacists, pursuant to an order or prescription. These standards are intended to apply to all sterile products, notwithstanding the location of the patient (e.g., home, hospital, nursing home, hospice, doctor's office).

History Note: Authority G.S. 90-85.6;

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Eff. October 1, 1990;
Amended Eff. April 1, 2003.

21 NCAC 46 .2802 DEFINITIONS

- (a) Anti-neoplastic. A pharmaceutical which causes the death of cancer or tumor cells.
- (b) Enteral. Within or by way of the intestine.
- (c) Parenteral. Sterile preparation of drugs for injection through one or more layers of the skin.
- (d) Sterile Pharmaceutical. A dosage form free from living microorganisms (aseptic).

History Note: Authority G.S. 90-85.6;
Eff. October 1, 1990.

21 NCAC 46 .2803 REQ/PHARMACIES DISPENSING STERILE PHARMACEUTICALS

All locations holding a pharmacy permit where sterile pharmaceuticals are routinely compounded for dispensing must meet the following requirements:

- (1) The location shall have a designated area with entry restricted to designated personnel for preparing compounded sterile products. This area shall be structurally isolated from other areas, with restricted entry or access, and must be designed to avoid unnecessary traffic and airflow disturbances from activity within the controlled facility. It shall be used only for the preparation of these specialty products. It shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.
- (2) The permit-holder preparing sterile products shall have the following equipment in addition to that required by Board Rule .1601 of this Chapter:
 - (a) Environmental control devices capable of maintaining at least Class 100 conditions in the work place where critical objects are exposed and critical activities are performed;
 - (b) Sink with hot and cold running water that is convenient to the compounding area for the purpose of hand scrubs prior to compounding;
 - (c) Disposal containers for used needles, syringes, etc., and if applicable cytotoxic waste from the preparation of chemotherapy agents and infectious wastes from patients' homes;
 - (d) When cytotoxic drug products are prepared, environmental control devices also include biohazard cabinetry;
 - (e) Refrigerator-freezer with a thermometer;
 - (f) Temperature controlled delivery containers; and
 - (g) Infusion devices, if appropriate.
- (3) The permit-holder dispensing sterile pharmaceuticals shall maintain inventories of the following supplies: Disposable needles, syringes, and other supplies needed for aseptic admixture; disinfectant cleaning solution; handwashing agents with bactericidal action; disposable, lint-free towels or wipes; appropriate filters and filtration equipment; oncology drug spill kit; and disposable masks, caps, gowns, and gloves.
- (4) In addition to the requirements of Rule .1601(a)(3) of this Chapter, a permit-holder dispensing sterile pharmaceuticals shall have in its reference library the following reference materials: Handbook on Injectable Drugs (ASHP); King's Guide to Parenteral Admixtures; American Hospital Formulary Service; and Procedure for Handling Cytotoxic Drugs (ASHP).

History Note: Authority G.S. 90-85.6;
Eff. October 1, 1990;
Amended Eff. April 1, 2003; September 1, 1995.

21 NCAC 46 .2804 RESPONSIBILITIES OF PHARMACIST-MANAGER

The pharmacist-manager of a permit-holder where sterile pharmaceuticals are prepared or dispensed must be knowledgeable in the specialized functions of preparing and dispensing compounded, sterile pharmaceuticals, including the principles of aseptic technique and quality assurance. The pharmacist-manager shall be responsible for the development and continuing review of all policies and procedures, training manuals, and quality assurance programs. Additionally, the pharmacist-manager is responsible for assuring that there is a system for disposal of infectious waste within the pharmacy in a manner so as not to endanger the public health.

History Note: Authority G.S. 90-85.6;
Eff. October 1, 1990;
Amended Eff. April 1, 2003.

21 NCAC 46 .2805 LABELING

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In addition to any other labeling requirements, containers of sterile pharmaceuticals dispensed to patients shall be labeled with instructions for storage to maintain sterility and, for anti-neoplastic drugs, appropriate warning labels.

History Note: Authority G.S. 90-85.6;
Eff. October 1, 1990;
Amended Eff. April 1, 2003.

21 NCAC 46 .2806 RECORDS AND REPORTS

The pharmacist-manager shall maintain access to and submit as appropriate such records and reports as are required to insure the patient's health, safety, and welfare. Such reports shall be readily available, maintained for three years, and subject to inspections by the Board or its agents.

History Note: Authority G.S. 90-85.6;
Eff. October 1, 1990.

21 NCAC 46 .2807 ANTI-NEOPLASTIC AGENTS

The following additional requirements are necessary for those permit-holders who prepare anti-neoplastic drugs:

- (1) All anti-neoplastic drugs shall be compounded in a vertical flow, Class II, biological safety cabinet, or similar appropriate preparation area. There must be strict adherence to the hood-cleaning procedures before preparing a product in the hood not classified as an anti-neoplastic agent.
- (2) Protective apparel shall be worn by personnel compounding anti-neoplastic drugs. This shall include disposable gloves and gowns with tight cuffs.
- (3) Appropriate safety and containment techniques for compounding anti-neoplastic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile parenteral products.
- (4) Disposal of anti-neoplastic waste shall comply with all applicable local, state, and federal requirements.
- (5) Written procedures for handling both major and minor spills of anti-neoplastic agents must be developed and must be included in the policy and procedural manual for the permit-holder.
- (6) Prepared doses of anti-neoplastic drugs must be dispensed, labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

History Note: Authority G.S. 90-85.6;
Eff. October 1, 1990;
Amended Eff. February 1, 2006.

21 NCAC 46 .2808 QUALITY ASSURANCE

There shall be a documented, ongoing quality assurance control program that monitors personnel performance, equipment and facilities. Appropriate samples of finished products shall be examined with such frequency as will assure that the pharmacy is capable of consistently preparing sterile products meeting specifications. Such examination shall include testing for microbial contamination. Quality assurance procedures shall include: recall procedures; storage and dating of products; maintenance of a log of the temperature of the refrigerator and/or freezer; routine maintenance and report of laminar flow hood certification; replacement on a regular basis of the pre-filters for the clean air source with documentation of the replacement dates; testing, with written documentation, of the end-product for microbial contamination; maintenance of written justification, or reference to published standards, for the chosen expiration date for compounded products; and regular quality assurance audits, including infection control and sterile technique audits.

History Note: Authority G.S. 90-85.6;
Eff. October 1, 1990;
Amended Eff. April 1, 2003.

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);

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Eff. October 1, 1991.

Amended Eff. July 1, 2011.

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.*

SECTION .3100 – CLINICAL PHARMACIST PRACTITIONER

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) "Joint Subcommittee" means the subcommittee composed of four members of the Pharmacy Board and four members of the Medical Board to whom responsibility is given by G.S. 90-6(c) to develop rules to govern the provision of drug therapy management by the Clinical Pharmacist Practitioner in North Carolina.
- (4) "Clinical Pharmacist Practitioner or CPP" means a licensed pharmacist who is approved to provide drug therapy management, including controlled substances, under the direction of, or under the supervision of a licensed physician who has provided written instructions for a patient and disease specific drug therapy which may include ordering, changing, substituting therapies or ordering tests. Only a pharmacist approved by the Pharmacy Board and the Medical Board may legally identify himself as a CPP.
- (5) "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 physician, patient, pharmacist and disease specific written agreement.
- (6) "Approval" means authorization by the Medical Board and the Pharmacy Board for a pharmacist to practice as a CPP in accordance with this Rule.
- (7) "Continuing Education or CE" is defined as courses or materials which have been approved for credit by the American Council on Pharmaceutical Education.
- (8) "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.

(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, which includes two years of clinical experience approved by the Boards; or

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- (ii) has successfully completed the course of study and holds the academic degree of Doctor of Pharmacy and 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) has successfully completed the course of study and holds the academic degree of Bachelor of Science in Pharmacy and 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 the fee to the Medical Board;
- (D) submits any information deemed necessary by the Medical Board in order to evaluate the application; and
- (E) has a signed supervising physician agreement.

If for any reason a CPP discontinues working in the approved physician arrangement, the CPP shall notify both Boards in writing within 10 days and the CPP's approval shall automatically terminate or be placed on an 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, 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 Medical Board upon verification of a full and unrestricted license to practice as a pharmacist in North Carolina.
 - (A) The application shall be approved and at the time of approval the Medical Board shall issue a number which shall be printed on each prescription written by the CPP; or
 - (B) The application shall be denied; or
 - (C) The application shall be approved with restrictions.

(c) Annual Renewal.

- (1) Each CPP shall register annually on the anniversary of his or her birth date by:
 - (A) verifying a current Pharmacist license;
 - (B) submitting the renewal fee as specified in Subparagraph (j)(2) of this Rule;
 - (C) completing the Medical Board's renewal form; and
 - (D) reporting continuing education credits as specified by the Medical Board.
- (2) If the CPP has not renewed within 30 days of the anniversary of the CPP's birth date, 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.

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- (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) The supervising physician who has a signed agreement with the CPP shall be readily available for consultation with the CPP and shall review and countersign each order written by the CPP within seven days.
 - (f) The written CPP agreement shall:
 - (1) be approved and signed by both the 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; 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) include a plan and schedule for weekly quality control, review and countersignature of all orders written by the CPP in a face-to-face conference between the physician and CPP;
 - (7) require that the patient be notified of the collaborative relationship; and
 - (8) be terminated when patient care is transferred to another physician and new orders shall be written by the succeeding physician.
 - (g) The supervising physician of the CPP 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. 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 if either Board finds one or more of the following:
 - (1) the CPP has held himself or herself out, or permitted another, to represent the CPP as 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 performed, or attempted to provide, medical management outside the approved drug therapy agreement or for which the CPP is not qualified by education and training to perform;
 - (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 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.
 - (2) The fee for annual renewal of approval, due on the CPP's anniversary of birth date is fifty dollars (\$50.00).
 - (3) No portion of any fee in this Rule is refundable.

History Note: Authority G.S. 90-6; 90-18; 90-18.4; 90-85.3; 90-85.18; 90-85.26A;
Eff. April 1, 2001;
Amended Eff. April 1, 2007; March 1, 2004; October 1, 2001.

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.

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History Note: Authority G.S. 90-85.6; 90-85.41;
Eff. April 1, 2001.

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.

21 NCAC 46 .3203 DUE PROCESS

Any action taken pursuant to a peer review agreement must afford the subject pharmacist or pharmacy technician all due process rights enumerated in the Administrative Procedure Act, G.S. 150B.

History Note: Authority G.S. 90-85.6; 90-85.41;
Eff. April 1, 2001;
Amended Eff. March 1, 2004.

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.

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.

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.

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.

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- (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.

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.

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.

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.

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.

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 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 more than 60 days shall be reinstated pursuant to 21 NCAC 46 .1612.
- (b) The current registration of a pharmacy technician shall be readily available for inspection by agents of the Board.

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- (c) The training program described in G.S. 90-85.15A(b) is not required for students enrolled in a community college pharmacy technician program.
- (d) Volunteer pharmacy technicians providing services at a facility which has a pharmacy permit designated as a free clinic shall complete the training program described in G.S. 90-85.15A(b) but need not register with the Board.
- (e) A pharmacist may not supervise more than two pharmacy technicians unless the additional pharmacy technicians have passed a national pharmacy technician certification examination administered by a provider whose examination assesses the ability of the technicians to function in accordance with G.S. 90-85.3(q2) and approved by the Board according to these standards.

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. June 1, 2006.

SECTION .3400 – AUTOMATED DISPENSING ON DRUG SUPPLY DEVICES

21 NCAC 46 .3401 DEFINITIONS

For purposes of these Rules, the following terms are defined as follows:

- (1) "Automated medication system" means a robotic, mechanical or computerized device that is not used for medication compounding and is designed to:
 - (a) Distribute medications in a licensed health care facility that holds a pharmacy permit; or
 - (b) Package medications for final distribution by a pharmacist.
- (2) "Centralized automated medication system" means an automated medication system located in a pharmacy department from which medication is distributed or packaged for final distribution by a pharmacist.
- (3) "Decentralized automated medication system" means automated medication systems that are located outside of a pharmacy department but within the same institution.
- (4) "Distribution" means the process of providing a drug to an individual authorized to administer medications and licensed as a health care provider in the state of North Carolina pursuant to an order issued by an authorized prescriber.
- (5) "Medication" means a medicinal drug or proprietary preparation.
- (6) "High risk override medication" means a single dose of medication that may be removed from a decentralized 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.
- (7) "Low risk override medication" is a medication determined by the Multidisciplinary Committee to have a low risk of drug allergy, drug interaction, dosing error, or adverse patient outcome, and may be removed from a decentralized automated medication system independent of a pharmacist's review of the medication order or clinical status of the patient.
- (8) "Physician controlled medication" is a medication ordered, prepared or administered by a physician.

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.

21 NCAC 46 .3402 GENERAL REQUIREMENTS FOR THE USE OF AUTOMATED MEDICATION SYSTEMS

General Requirements for the Use of Automated Medication Systems include the following:

- (1) The consultant pharmacist of record or pharmacist-manager shall be responsible for:
 - (a) Maintaining a record of each transaction or operation;
 - (b) Controlling access to the system;
 - (c) Maintaining policies and procedures for:
 - (i) Operating of the automated medication system;
 - (ii) Training personnel who use the automated medication system;
 - (iii) Maintaining patient services whenever the automated medication system is not operating; and
 - (iv) Defining a procedure for a pharmacist to grant access to the medication in the system or to deny access to the medication in the system.
 - (d) Security of the system;

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- (e) Assuring that a patient receives the pharmacy services necessary for good pharmaceutical care in a timely manner;
 - (f) Assuring that the system maintains the integrity of the information in the system and protects patient confidentiality;
 - (g) Establishing a comprehensive Quality Assurance program;
 - (h) Establishing a procedure for stocking or restocking the automated medication system; and
 - (i) Insuring compliance with all requirements for packaging and labeling.
- (2) A pharmacist shall perform prospective drug use review and approve each medication order prior to administration of a medication except a high risk override medication, a low risk override medication or a physician controlled medication.
- (3) A pharmacist shall perform retrospective drug use review for a high risk override medication and a low risk override medication.

History Note: Authority G.S. 90-85.6; 90-85.32; 90-85.33;
Eff. February 1, 2005.

21 NCAC 46 .3403 MULTIDISCIPLINARY COMMITTEE FOR DECENTRALIZED AUTOMATED MEDICATION SYSTEMS

- (a) The consultant pharmacist of record or pharmacist-manager shall convene or identify a multidisciplinary committee, which is charged with oversight of the decentralized automated medication system.
- (b) The Multidisciplinary Committee shall:
- (1) Include at least one pharmacist;
 - (2) Establish the criteria and process for determining which medication qualifies as a high risk override medication or a low risk override medication in a decentralized automated medication system; and
 - (3) Develop policies and procedures regarding the decentralized automated medication system.

History Note: Authority G.S. 90-85.6; 90-85.32; 90-85.33;
Eff. February 1, 2005.

21 NCAC 46 .3404 STOCKING OR RESTOCKING OF AN AUTOMATED MEDICATION SYSTEM

- (a) Medications in an Automated Medication System shall be stocked or restocked by a pharmacist or by a pharmacy technician supervised by a pharmacist as satisfied by Paragraph (d)(2) of this Rule.
- (b) The stocking or restocking of an automated medication system shall follow one of the following procedures to ensure correct medication selection:
- (1) A pharmacist shall conduct and document a daily audit of medications placed or to be placed into an automated medication system that may include random sampling.
 - (2) A bar code verification, electronic verification, or similar verification process shall be utilized to assure correct selection of medication placed or to be placed into an automated medication system. The utilization of a bar code, electronic, or similar verification technology shall require an initial quality assurance validation, followed by a quarterly quality assurance review by a pharmacist.
- (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 medication stocking, restocking or verification process.
- (d) Medication Reuse. Medication that has been removed from the automated medication system shall not be replaced into the system unless:
- (1) a pharmacist has examined the medication, the packaging, and the labeling and determined that reuse of the medication is appropriate; or
 - (2) specific medications, 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.

21 NCAC 46 .3405 CENTRALIZED AUTOMATED MEDICATION SYSTEMS

A pharmacist utilizing a centralized automated medication system may distribute patient specific medications within the licensed health care facility without checking each individual medication selected or packaged by the system, if :

- (1) The initial medication order has been reviewed and approved by a pharmacist; and
- (2) The medication is distributed for subsequent administration by a health care professional permitted by North Carolina law to administer medication.

History Note: Authority G.S. 90-85.6; 90-85.32; 90-85.33;
Eff. February 1, 2005.

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21 NCAC 46 .3406 QUALITY ASSURANCE PROGRAM

The consultant pharmacist of record or pharmacist-manager shall be responsible for establishing a quality assurance program for the automated medication system. The program shall provide for:

- (1) Review of high risk override medication and low risk override medication utilization;
- (2) Investigation of a medication error related to the automated medication system;
- (3) Review of a discrepancy or transaction reports and identification of patterns of inappropriate use or access;
- (4) Review of the operation of the 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.

History Note: Authority G.S. 90-85.6; 90-85.32; 90-85.33;
Eff. February 1, 2005.

21 NCAC 46 .3407 RECORD KEEPING

(a) The consultant pharmacist of record or pharmacist-manager shall maintain records related to the automated medication system for the system in a readily retrievable manner.

(b) The following records shall be maintained for at least three years.

- (1) Daily audits of stocking or restocking, if applicable;
- (2) Daily audits of the output of a centralized automated medication system, if applicable; and
- (3) Transaction records for all non-controlled medications or devices distributed by the automated medication system.

(c) The following records shall be maintained for at least three years:

- (1) Any report or analysis generated as part of the quality assurance program;
- (2) A report or database related to access to the system or any change in the access to the system or access to medication in the system; and
- (3) Transaction records from the automated medication system for all controlled substances dispensed or distributed.

History Note: Authority G.S. 90-85.6; 90-85.32; 90-85.33;
Eff. February 1, 2005.

21 NCAC 46 .3408 COMPLIANCE

The consultant pharmacist of record or pharmacist-manager shall assure compliance with all requirements of the Pharmacy Practice Act and Board rules.

History Note: Authority G.S. 90-85.6; 90-85.32; 90-85.33;
Eff. February 1, 2005.