SECTION .1400 - HOSPITALS: OTHER HEALTH FACILITIES

21 NCAC 46 .1401 REGISTRATION AND PERMITS

(a) Registration Required. All places providing services which embrace the practice of pharmacy shall register with the North Carolina Board of Pharmacy as provided in G.S. 90-85.21 and acquire a permit to do so. Application for such registration and permit shall be on forms provided by the Board. If the Board is satisfied that proper facilities and adequately trained and properly licensed personnel have been obtained which will assure compliance with all laws regulating the compounding and distribution of drugs, the practice of pharmacy and the rules of the Board, a permit shall be issued by the Board attesting such registration.

(b) Exemptions. Nothing in these rules shall be construed to require the registration with the Board of those health care facilities in which there occurs only the administration of drugs.

(c) Separate Registration Required. The dispensing of drugs from separate locations owned by a health care facility, such as satellite pharmacies, outside clinics, health maintenance organizations, or physician's offices owned by the health care facility shall require separate registration if any one of the following criteria exists:

(1) The drugs dispensed at the location are ordinarily and customarily obtained from a source outside of the health care facility;

(2) The pharmacist-manager is controlled and supervised from a source other than the health care facility pharmacy; or

(3) The routine activity at the location is dispensing drugs to outpatients.

(d) Any pharmacy that provides compounding or dispensing services to one or more health care facilities for individual patient administration bearing any labeled name other than that under which it is registered shall require a separate registration.

(e) Health care facilities which do not have a pharmacy permit shall secure their pharmaceutical services through a pharmacist holding a current license from the Board.

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

21 NCAC 46 .1402 SUPERVISION OF DRUGS IN AREAS OUTSIDE OF PHARMACY

21 NCAC 46 .1403 INSTITUTIONAL PHARMACY DRUG INVENTORIES AND EMERGENCY KITS

21 NCAC 46 .1404 MEDICATION IN INSTITUTIONAL EMERGENCY DEPARTMENTS

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Repealed Eff.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

21 NCAC 46 .1405 STANDARDS FOR PHARMACY SERVICE

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

21 NCAC 46 .1406 AUTOMATIC STOP ORDERS

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

21 NCAC 46 .1407 INSTITUTIONAL FORMULARY

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

21 NCAC 46 .1408 INSTITUTIONAL DISCHARGE MEDICATION OPTION

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

21 NCAC 46 .1409 RESEARCH PARTICIPATION

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

21 NCAC 46 .1410 PERSONNEL

(a) The health care facility pharmacy must be directed by a legally qualified pharmacist, hereinafter referred to as the pharmacist-manager, who shall be responsible for meeting the requirements set forth by Federal and State law, this Section, 21 NCAC 46.2502, and other applicable Rules of the Board. The pharmacist-manager shall be thoroughly familiar with the specialized functions of health care facility pharmacy practice. The pharmacist-manager shall be an employee of the health care facility or contracted for by the health care facility in which the pharmacy is located.

(b) The pharmacist-manager shall be assisted by a sufficient number of pharmacists and supportive personnel to operate such pharmacy competently, safely, and to meet the needs of the patients of the health care facility.

(c) The pharmacist-manager shall ensure that an adequate number of qualified and trained pharmacists are employed. The pharmacist- manager shall develop and implement written policies and procedures to specify the duties to be performed by such pharmacists.

(d) The pharmacist-manager shall ensure that a sufficient number of qualified, trained, and adequately supervised supportive personnel are employed to provide technical services, as well as ensuring that all such functions and activities are performed competently, safely, and without risk of harm to patients. The relationship between the supervising pharmacist and the supportive personnel shall be such that the pharmacist is fully aware of and responsible for all activities involved in the preparation and dispensing of medications prior to release to the patient, including the maintenance of appropriate records.

(e) Secretarial and clerical support shall be provided to assist with record keeping, report submission and other administrative duties.

History Note: Authority G.S. 90-85.6; 90-85.21;
Eff. May 1, 1997.

21 NCAC 46 .1411 RESPONSIBILITIES OF THE PHARMACIST-MANAGER

(a) The pharmacist-manager shall establish written procedures for the safe and effective distribution of pharmaceutical products. Procedures shall be reviewed annually to assure they reflect current practice in the facility. A copy of such procedures shall be available in the pharmacy.

(b) The pharmacist-manager is responsible for the safe and effective distribution of, control over and accountability for drugs, including intravenous and irrigation solutions. The pharmacist-manager may delegate responsibilities to other health care facility staff for ordering, distributing, and accounting for pharmaceutical materials to achieve this purpose. Whenever there is a violation of the rules in this Section, the facility's pharmacy permit is subject to action by the Board. In addition to the requirements of 21 NCAC 46 .2502, the pharmacist-manager is responsible for:

(1) the development of policies and procedures for the compounding, admixture, labeling, and dispensing of parenteral medications in the health care facility, including relevant education and training of all pharmacy and nursing personnel involved in the preparation of parenteral medications;

(2) the establishment of specifications or use of compendia specifications for procurement of all pharmaceuticals, including drugs, chemicals, and biologicals used in direct patient care, subject to approval of the appropriate committee of the health care facility;
(3) participation in development and maintenance of a drug formulary when required by the health care facility;
(4) participation in those aspects of pharmaceutical care that affect drug distribution and control;
(5) preparing, packaging, compounding and labeling all drugs;
(6) assuring that drugs are dispensed only by a pharmacist or other persons allowed by law to dispense and that supportive pharmacy personnel are directed and supervised in compliance with all applicable laws and regulations;
(7) the development and implementation of policies and procedures to ensure that discontinued drugs; outdated drugs; drugs recalled; containers with worn, illegible, or missing labels; or products that are otherwise unusable are returned to the pharmacy for disposition in compliance with all applicable laws and regulations;
(8) maintaining records and reports required by law to ensure patient health, safety and welfare;
(9) developing and implementing policies and procedures that effectively address the safeguarding and handling of all drugs and devices, as defined in G.S. 90-85.3(e), throughout the health care facility, or other locations where legend drug products are transferred, including medications that originate from a source outside the facility. When discrepancies in controlled substance counts are identified:
    (A) they shall be reviewed, and a report of this action, including steps taken to prevent recurrence, where possible, shall be provided to the pharmacist-manager within 24 hours of occurrence. This report shall be maintained by the pharmacist-manager; and
    (B) they shall be reported to the Board and the Drug Enforcement Administration in compliance with all applicable laws and regulations;
(10) developing and implementing policies and procedures to ensure that auxiliary medication inventories are inspected in accordance with the pharmacy's policies;
(11) all drugs and devices dispensed by the pharmacy as defined in G.S. 90-85.3(e) that are ordered for and used within the health care facility; and
(12) maintaining policies and procedures regarding drug samples and patient's personal medications.

History Note: *Authority G.S. 90-85.6; 90-85.21; 90-85.32;*
Eff. May 1, 1997;
Amended Eff. March 1, 2013.

21 NCAC 46 .1412 PHYSICAL REQUIREMENTS

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

(1) Dispensing areas;
(2) Compounding areas that comply with Section .2800 of this Chapter;
(3) Receiving and storage areas;
(4) Packaging and repackaging areas;
(5) Office space sufficient to allow for administrative functions without interference with the safe compounding and dispensing of medications and security of the pharmacy;
(6) Storage. All drugs shall be stored in designated areas within the pharmacy or decentralized pharmacy sufficient to provide sanitation to prevent contamination, moisture control, and security to prevent access from unauthorized personnel. Controlled substances shall be stored in compliance with applicable Federal and State laws and regulations. Alcohol and flammables shall be stored in areas that shall meet basic local building code requirements for the storage of volatile substances and all other laws, ordinances, or regulations that may apply; and
(7) Security. All areas occupied by the health care facility pharmacy, to include

auxiliary drug supplies and unit dose carts, shall remain secured at all times.

History Note: *Authority G.S. 90-85.6; 90-85.21; 90-85.32;*
Eff. May 1, 1997;
Amended Eff. January 1, 2015; March 1, 2013.

21 NCAC 46 .1413 ABSENCE OF PHARMACIST

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

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

(2) a nurse trained and authorized by the pharmacist-manager to remove drugs or devices from the pharmacy in the absence of a pharmacist. Entry into the pharmacy in the absence of a pharmacist shall occur only if the drug needed is not in the auxiliary medication inventory. The pharmacist-manager shall maintain a current list of authorized persons and document the initial orientation, continuing education, and quality control processes on an ongoing basis. The pharmacist-manager shall maintain a list of restricted medications that shall not be taken from the pharmacy and may only be removed after contacting the "on call" pharmacist to verify the appropriateness and accuracy of the medication order and medication removed from the pharmacy at the time of removal. For medications not on the restricted list, an "on call" pharmacist must be accessible for questions by the authorized nurse. Within 24 hours, a pharmacist shall verify the accuracy and appropriateness of the medication order and the medication removed from the pharmacy.

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

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

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

History Note: *Authority G.S. 90-85.6; 90-85.21; 90-85.32; 90-85.33; 90-85.34;*
Eff. May 1, 1997;
Amended Eff. March 1, 2013; August 1, 2000.

21 NCAC 46 .1414 DRUG DISTRIBUTION AND CONTROL

(a) MEDICATION ORDERS.

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

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

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

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

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

(D) date the order was written; and

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

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

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

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

(C) medication start date;

(D) medication discontinuance date; and

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

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

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

(A) the routine monitoring of patient's drug therapy by a pharmacist;

(B) a health care facility-approved, drug class-specific, automatic stop order policy covering those drug orders not specifying a number of doses or duration of therapy; or

(C) a health care facility-approved automatic cancellation of all medication orders after a predetermined time interval unless rewritten by the prescriber.

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

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

(c) LABELING.

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

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

(d) AUXILIARY MEDICATION INVENTORIES.

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

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

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

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

devices contained within an auxiliary medication inventory, including the name, strength, and quantity of each, shall be attached.

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

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

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

(e) RESERVED.

(f) RESERVED.

(g) RESERVED.

(h) RESERVED.

(i) RESERVED.

(j) RECORDS.

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

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

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

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

(D) A record of controlled substances dispensed directly to the patient to include the patient's name; date dispensed; dispensing pharmacist's name; name, strength, dosage form, and quantity of the drug dispensed. The records shall also document drugs returned and credited; and

(E) A perpetual inventory on all controlled substances awaiting destruction or return to a vendor.

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

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

History Note: *Authority G.S. 90-85.6; 90-85.21; 90-85.32; 90-85.33; 90-85.34;*
Eff. May 1, 1997;
Amended Eff. March 1, 2013; February 1, 2005; April 1, 2003; April 1, 1999; August 1, 1998.

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

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

(b) When drugs are not otherwise available from a pharmacist, drugs may be dispensed for use outside the emergency department by the physician, registered nurse under physician supervision, or a person authorized to prescribe and dispense drugs pursuant to G.S. 90-18.1 or 90-18.2 subject to the following:

(1) Drugs shall be dispensed only to a registered patient of the emergency department;

(2) The pharmacist-manager shall develop and supervise a system of control and accountability of all drugs administered in, or dispensed from the emergency department;

(3) The pharmacist-manager, in conjunction with the committee responsible for policy in the emergency department, shall develop an emergency department formulary which may be dispensed from the emergency department for patients receiving care in that department. This formulary shall consist of drugs of the nature and type to meet the immediate needs of emergency department patients, and quantities in each container shall be limited to not more than a 24 hour supply or the smallest commercially-available quantity;

(4) Drugs shall be prepackaged in safety closure containers and shall be pre-labeled by the pharmacist to comply with Rule .1414(d)(4) of this Section. Prior to dispensing, the following information shall be placed on the label:

(A) the name, address, and telephone number of the health care facility pharmacy;

(B) the dispensing date;

(C) the full name of patient;

(D) the generic or trade name, or in the absence of a brand name, the established name of the product dispensed;

(E) directions for use to the patient;

(F) the name of physician prescribing and dispensing the product; and

(G) required precautionary or further accessory cautionary information as may be desirable for proper use and safety to the patient;

(5) A perpetual record of dispensing of all drugs, including drug samples and starter packages, shall be maintained as part of the pharmacy's records for three years. The pharmacist-manager or designee shall verify the accuracy of these records at least once a month. The record shall contain the following:

(A) the date dispensed;

(B) the patient's name;

(C) the physician's name; and

(D) the name, strength, dosage form, quantity, and dose of the drug dispensed.

(6) The physician shall sign all orders for medication within the time frame established by regulatory agencies and health care facility policies and procedures.

(c) The physician, registered nurse under physician supervision, or person who is authorized to prescribe and dispense drugs pursuant to G.S. 90-18.1 or 90-18.2 shall comply with all rules governing the dispensing of

medications including patient counseling as defined in 21 NCAC 46 .2504.

History Note: *Authority G.S. 90-85.6; 90-18.1; 90-18.2; 90-85.21; 90-85.32; 90-85.33;*
Eff. May 1, 1997;
Amended Eff. March 1, 2013.

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 Rule is to set out requirements under which health care facility pharmacies may contract for the provision of remote medication order processing services.

(b) Definitions of terms in this Rule:

(1) "Remote medication order processing services" consists of the following:
  (A) receiving, interpreting, or clarifying medication orders;
  (B) entering data and transferring medication order information;
  (C) performing drug regimen review;
  (D) interpreting clinical data;
  (E) performing therapeutic interventions; and
  (F) providing drug information concerning medication orders or drugs.
(2) "Remote medication order processing pharmacy" is a pharmacy permitted by the Board that provides remote medication order processing services.
(3) "Remote site" is a site located within the United States that is electronically linked to a health care facility licensed by the State of North Carolina for the purpose of providing remote medication order processing services.

(c) Outsourcing. A health care facility pharmacy may outsource medication order processing services to a remote medication order processing pharmacy provided the pharmacies have the same owner or the pharmacy has entered into a written contract or agreement with a remote medication order processing pharmacy 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 shall 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 outsourcing 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. The 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.

(1) The pharmacies shall share common electronic files or have technology to allow secure access to the pharmacy's information system and to provide the remote site with access to the information required to process a medication order.
(2) Pharmacists employed by or otherwise acting as an agent for a remote medication order processing pharmacy may provide those services from a remote site. Both the pharmacist providing those services from a remote site and the remote medication order processing pharmacy on whose behalf the pharmacist is providing such services are responsible for compliance with all statutes, rules, policies, and procedures governing the provision of remote mediation order processing services.

(f) Communication. The pharmacies shall 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 shall maintain records of all orders entered into their information system including orders entered from a remote site. The system shall have the ability to audit the activities of the individuals remotely processing medication orders.

(h) Licensure. All remote medication order processing pharmacies shall be permitted by the Board. An out-of-state remote medication order processing pharmacy 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 remote medication order processing pharmacy providing services in this State shall be licensed by the Board.

(i) Policy and Procedure Manual. All remote medication order processing pharmacies shall maintain a policy and procedure manual. Each remote medication order processing pharmacy, remote site, and health care facility pharmacy shall maintain those portions of the policy and procedure manual that relate to that pharmacy's or site'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 permit 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 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 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.

(j) Nothing in this Rule shall be construed to relieve a health care facility pharmacy of the need to provide on-site pharmacy services required for licensure as specified in the Pharmacy Practice Act and rules promulgated thereunder.

History Note: *Authority G.S. 90-85.6; 90-85.21; 90-85.21A; 90-85.26; 90-85.32; 90-85.34;*
Eff. February 1, 2006;
Amended Eff. December 1, 2015; March 1, 2013.

21 NCAC 46 .1418 SUPERVISION OF UNIT DOSE MEDICATION SYSTEMS

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

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

(1) permit a Validating Technician to validate only the following functions of other registered pharmacy technicians in filling floor stock and unit dose distribution systems for inpatients in a Hospital:

(A) stocking of patient care unit medication inventories;

(B) stocking of ancillary drug cabinet inventories;

(C) stocking of automated dispensing or drug supply devices;

(D) stocking of emergency kits; and

(E) prepackaging of prescription drugs within the Hospital pharmacy;

(2) establish the parameters for pharmacist supervision of pharmacy technician validation functions;

(3) establish facility-specific training for pharmacy technician validation functions;

(4) establish an ongoing evaluation and assessment program to ensure that pharmacy technician validation functions are performed safely and accurately; and

(5) establish a recordkeeping system that shall permit the identification of the Validating Technician who performs activities authorized by this Rule. Readily retrievable records generated by this system shall be maintained for the period of time specified in 21 NCAC 46 .1414(j)(1) and (2).

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

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

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

(1) is registered with the Board and trained as specified in G.S. 90-85.15A;

(2) is a certified technician;

(3) holds either:

(A) an associate's degree in pharmacy technology conferred by either an institution within the North Carolina Community College System or System;

(B) an associate's degree in pharmacy technology conferred by an institution accredited by one of the regional accrediting agencies recognized by the United States Department of Education; or

(C) an associate's degree in pharmacy technology conferred by a program accredited by the American Society of Health System Pharmacists; and

(4) assists pharmacists with the preparation, dispensing and distribution of prescription medications that will be administered by a licensed health care provider to an inpatient in a Hospital under this Rule.

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

(1) a hospital licensed by the North Carolina Medical Care Commission; or

(2) a psychiatric hospital operated by the Secretary of the Department of Health and Human Services.

(g) Pursuant to G.S. 90-85.15A(c), the Board approves a pharmacist's supervision of more than two pharmacy technicians where the additional technicians are Validating Technicians. This Rule does not relieve the pharmacist-manager of the obligation to request and receive written Board approval for a pharmacist's supervision of more than two pharmacy technicians where the additional technicians are certified pharmacy technicians but are not Validating Technicians.

(h) A pharmacy technician performing validation functions described in this Rule as part of a Board-approved 21 NCAC 46 .2510 pilot project at Broughton State Hospital or Wake Forest University Baptist Medical Center may continue to perform such functions for a period of three years from this Rule's original effective date, after which time the pharmacy technician must meet all of the requirements specified in Paragraph (e) of this Rule to continue performing such functions.

History Note: *Authority G.S. 90-85.6; 90-85.15A; 90-85.21; 90-85.26; 90-85.32; 90-85.33; 90-85.34; Eff. June 18, 2011.*