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;*
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