

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;
 - (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.

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.