

SECTION .3400 – AUTOMATED DISPENSING ON DRUG SUPPLY DEVICES

21 NCAC 46 .3401 DEFINITIONS

For purposes of this Section, the following terms are defined as follows:

- (1) "Automated medication system" means a robotic, mechanical, or computerized device that is not used for drug compounding and is designed to:
 - (a) Distribute drugs in a licensed health care facility that holds a pharmacy permit; or
 - (b) Package drugs for final distribution by a pharmacist.
- (2) "Distribution" means the process of providing a drug to an individual authorized to administer drugs and licensed as a health care provider in the state of North Carolina pursuant to an order issued by an authorized prescriber.
- (3) "Override medication" means:
 - (a) A drug that may be removed from an automated medication system prior to pharmacist review because the Multidisciplinary Committee has determined that the clinical status of the patient would be compromised by delay; or
 - (b) A drug determined by the Multidisciplinary Committee to have a low risk of drug allergy, drug interaction, dosing error, or adverse patient outcome, which may be removed from an automated medication system independent of a pharmacist's review of the medication order or clinical status of the patient.
- (4) "Physician controlled medication" is a drug ordered, prepared and administered by a physician or under the physician's direct supervision.

History Note: Authority G.S. 90-85.6; 90-85.32; 90-85.33;
Eff. April 1, 1999;
Amended Eff. February 1, 2005; August 1, 2002;
Recodified from 21 NCAC 46 .1814 Eff. February 1, 2005;
Amended Eff. December 1, 2013.

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

- (a) The pharmacist-manager shall assure compliance with all requirements of the Pharmacy Practice Act and this Section.
- (b) The pharmacist-manager shall be responsible for:
 - (1) Maintaining a record of each transaction or operation;
 - (2) Controlling access to the automated medication system;
 - (3) Maintaining policies and procedures for:
 - (A) Operating the automated medication system;
 - (B) Training personnel who use the automated medication system;
 - (C) Maintaining patient services whenever the automated medication system is not operating; and
 - (D) Defining a procedure for a pharmacist to grant access to the drugs in the automated medication system or to deny access to the drugs in the automated medication system.
 - (4) Securing the automated medication system;
 - (5) Assuring that a patient receives the pharmacy services necessary for appropriate pharmaceutical care;
 - (6) Assuring that the automated medication system maintains the integrity of the information in the system and protects patient confidentiality;
 - (7) Establishing a procedure for stocking or restocking the automated medication system; and
 - (8) Insuring compliance with all requirements for packaging and labeling.
- (c) A pharmacist shall perform prospective drug use review and approve each medication order prior to administration of a drug except an override medication or a physician controlled medication.
- (d) A pharmacist shall perform retrospective drug use review for an override medication.
- (e) The pharmacist-manager shall convene or identify a Multidisciplinary Committee, which is charged with oversight of the automated medication system. The Multidisciplinary Committee shall:
 - (1) Include the pharmacist-manager or the pharmacist-manager's designee;

- (2) Establish the criteria and process for determining which drug qualifies as an override medication; and
 - (3) Develop policies and procedures regarding the operation of the automated medication system.
- (f) A pharmacy utilizing an automated medication system may distribute patient-specific drugs within the health care facility without verifying each individual drug selected or packaged by the system, if:
- (1) The initial medication order has been reviewed and approved by a pharmacist; and
 - (2) The drug is distributed for subsequent administration by a health care professional permitted by North Carolina law to administer drugs.
- (g) The pharmacist-manager shall be responsible for establishing a quality assurance program for the automated medication system. The program shall provide for:
- (1) Review of override medication utilization;
 - (2) Investigation of any medication error related to drugs distributed or packaged by the automated medication system;
 - (3) Review of any discrepancy or transaction reports and identification of patterns of inappropriate use or access of the automated medication system;
 - (4) Review of the operation of the automated medication system;
 - (5) Integration of the automated medication system quality assurance program with the overall continuous quality improvement program of the pharmacy; and
 - (6) Assurance that individuals working with the automated medication system receive appropriate training on operation of the system and procedures for maintaining pharmacy services when the system is not in operation.
- (h) The pharmacist-manager shall maintain, for at least three years, the following records related to the automated medication system in a readily retrievable manner:
- (1) Transaction records for all non-controlled drugs or devices distributed by the automated medication system;
 - (2) Transaction records from the automated medication system for all controlled substances dispensed or distributed; and
 - (3) Any report or analysis generated as part of the quality assurance program required by Paragraph (g) of this Rule.

History Note: Authority G.S. 90-85.6; 90-85.32; 90-85.33;
 Eff. February 1, 2005;
 Amended Eff. December 1, 2013.

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

History Note: Authority G.S. 90-85.6; 90-85.32; 90-85.33;
 Eff. February 1, 2005;
 Repealed Eff. December 1, 2013.

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

- (a) Responsibility for accurate stocking and restocking of an automated medication system lies with the pharmacist-manager and with any pharmacist tasked with supervising such functions as specified in Subparagraph (b)(2) of this Rule.
- (b) The stocking or restocking of an automated medication system, where performed by someone other than a pharmacist, shall follow one of the following procedures to ensure correct drug selection:
- (1) A pharmacist shall conduct and document a daily audit of drugs placed or to be placed into an automated medication system by a pharmacy technician, which audit may include random sampling.
 - (2) A bar code verification, electronic verification, or similar verification process shall be utilized to assure correct selection of drugs placed or to be placed into an automated medication system. The utilization of a bar code, electronic, or similar verification process shall require an initial quality assurance validation, followed by a quarterly quality assurance review by a pharmacist. When a bar code verification, electronic verification, or similar verification process is utilized as specified

in this section, stocking and restocking functions may be performed by a pharmacy technician or by a registered nurse trained and authorized by the pharmacist-manager.

(c) The pharmacist performing the quality assurance review shall maintain a record of the quality assurance process that occurred and the pharmacist approval of the drug stocking, restocking or verification process.

(d) Medication Reuse. Any drug that has been removed from the automated medication system shall not be replaced into the system unless:

- (1) the drug's purity, packaging, and labeling have been examined according to policies and procedures established by the pharmacist-manager to determine that reuse of the drug is appropriate; or
- (2) specific drugs, such as multi-dose vials, have been exempted by the Multidisciplinary Committee.

History Note: Authority G.S. 90-85.6; 90-85.32; 90-85.33;
Eff. February 1, 2005;
Amended Eff. December 1, 2013.

21 NCAC 46 .3405 CENTRALIZED AUTOMATED MEDICATION SYSTEMS
21 NCAC 46 .3406 QUALITY ASSURANCE PROGRAM
21 NCAC 46 .3407 RECORD KEEPING
21 NCAC 46 .3408 COMPLIANCE

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