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;*
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