Title 10

MARYLAND DEPARTMENT OF HEALTH

Subtitle 34 BOARD OF PHARMACY

10.34.28 Automated Medication Systems

Authority: Health Occupations Article, §§12-205(a) and 12-605, Annotated Code of Maryland

.01 Scope.

This chapter defines the parameters under which a permit holder may allow the use of automated medication systems to facilitate the dispensing and distribution of medication.

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Automated medication system" means a centralized, decentralized, or remote robotic or computerized device and that device's components designed to:

(a) Distribute medications in a licensed health care facility, a related institution as defined in Health-General Article, §19-301, Annotated Code of Maryland, or a medical facility owned and operated by a group model health maintenance organization as defined in Health-General Article, §19-713.6, Annotated Code of Maryland; or

(b) Prepare medications for final dispensing by a licensed pharmacist.

(2) "Centralized automated medication system" means an automated medication system located in a pharmacy from which medication is distributed or prepared for final dispensing by a licensed pharmacist for a specific patient.

(3) "Decentralized automated medication system" means an automated medication system that is located outside of the pharmacy in a health care facility, a related institution as defined in Health-General Article, §19-301, Annotated Code of Maryland, or a medical facility owned and operated by a group model health maintenance organization as defined in Health-General Article, §19-713.6, Annotated Code of Maryland, with an on-site pharmacy and in which medication is stored in a manner that may be, but need not be, patient specific.

(4) "Distribution" means the process resulting in the provision of a prescription or nonprescription drug or device to a separate, intervening individual, licensed and practicing under Health Occupations Article, Annotated Code of Maryland, before the administration of the provided drug or device to a patient and pursuant to an order issued by an authorized prescriber.

(5) “Health care facility” means a hospital or related institution as defined in Health-General Article, §19-301, Annotated Code of Maryland.

(6) “Interim box” means a tamper evident and secure container or secure electronic storage system holding minimal quantities of medications agreed on by the health care facility intended to expedite immediate initiation of emergency or nonemergency dosing until the pharmacy is able to provide a regular supply.

(7) Remote Automated Medication System.

(a) "Remote automated medication system" means an automated medication system that is located in a health care facility, a related institution as defined in Health-General Article, §19-301, Annotated

Code of Maryland, or a medical facility owned and operated by a group model health maintenance organization as defined in Health-General Article, §19-713.6, Annotated Code of Maryland, that does not have an on-site pharmacy and in which medication is stored in a manner that may be, but need not be, patient specific.

(b) "Remote automated medication system" does not include an interim box or other similar medication storage container that:

(i) Does not operate pursuant to the entry of a medication order;

(ii) Does not require a pharmacist's review before access to medication;

(iii) Is stocked with unit dose medications;

(iv) Has the sole purpose of providing a medication dosage pending the next pharmacy delivery to the health care facility;

(v) Is located in a patient care setting that does not have a pharmacy on site; and

(vi) Is stocked and controlled by a pharmacy providing services to a health care facility.

(8) "Responsible pharmacist" means a licensed pharmacist who ensures the safe and efficient dispensing, repackaging, delivery, control, positive drug identification including bar coding, transaction records, dispensation records, labeling, and accountability for medications in an automated medication system.

(9) "Starter dose" means a dose of medication removed from a remote or decentralized automated medication system within the first 24 hours after it is ordered.

(10) "Unit dose" means a medication container or package containing one discrete pharmaceutical dosage form labeled according to federal and State law.

.03 Limitation on Privileges to Administer.
In this chapter, "privileges to administer medication" does not include privileges created by delegation from a licensed health care professional to an unlicensed health care professional.

.04 Usage Requirements for Centralized Automated Medication Systems.
A. An automated medication system may only be used if:

(1) Records concerning transactions or operations are maintained in accordance with Regulation .11 of this chapter;

(2) A responsible pharmacist has been designated by the permit holder to supervise and manage the operations of the centralized automated medication system; and

(3) The permit holder ensures that:

(a) Patients have prompt access to pharmacy services necessary for the provision of good pharmaceutical care as defined in Health Occupations Article, §12-101, Annotated Code of Maryland;

(b) The centralized automated medication system maintains the integrity of the information in the system and protects patient confidentiality; and

(c) The centralized automated medication system is subject to a quality assurance program in accordance with Regulation .10 of this chapter.

B. A permit holder shall indicate on the initial, renewal, and reinstatement applications:

(1) Whether the permit holder operates a centralized automated medication system; and

(2) Any other information regarding the system that the Board considers necessary to determine compliance with this chapter.

.05 Usage Requirements for Decentralized Automated Medication Systems.

A. A decentralized automated medication system may only be used if:

(1) Records concerning transactions or operations are maintained in accordance with Regulation .11 of this chapter;

(2) A responsible pharmacist has been designated by the permit holder to supervise and manage the operations of the automated medication system;

(3) Except for starter doses, a licensed pharmacist reviews each order for medication:

(a) After the order has been entered into the system; and

(b) Before the system permits access to the medication;

(4) The permit holder ensures that:

(a) Patients have prompt access to pharmacy services necessary for the provision of good pharmaceutical care as defined in Health Occupations Article, §12-101, Annotated Code of Maryland;

(b) The decentralized automated medication system maintains the integrity of the information in the system and protects patient confidentiality; and

(c) The decentralized automated medication system is subject to a quality assurance program in accordance with Regulation .10 of this chapter; and

(5) It is designed to distribute medications in a licensed health care facility, a related institution as defined in Health-General Article, §19-301, Annotated Code of Maryland, or a medical facility owned and operated by a group model health maintenance organization as defined in Health-General Article, §19-713.6, Annotated Code of Maryland.

B. A starter dose, or a dose in response to an emergency, may be distributed without prior review by a pharmacist of the order if:

(1) The pharmacist reviews the order within 24 hours of removal from the decentralized automated medication system; or

(2) The prescriber reviews the patient medical history and authorizes the administration of the dose to the patient.

C. Decentralized automated medication systems shall operate in a manner which:

(1) Limits simultaneous access to multiple:

(a) Drug strengths;

(b) Dosage forms; or

(c) Drug entities;

(2) Prevents access to medications not ordered for the patient; and

(3) Safeguards against the misidentification of medications, dosages, and dosage forms by those accessing the decentralized automated medication system.

D. The requirements listed in §C(1) and (2) of this regulation do not apply to automated supply towers which contain:

(1) Noncontrolled medications that are:

(a) Refrigerated;

(b) Bulk; or

(c) Intravenous fluids; or

(2) Prescription devices.

E. A permit holder shall indicate on the initial, renewal, and reinstatement applications:

(1) Whether the permit holder operates a decentralized automated medication system; and

(2) Any other information regarding the system that the Board considers necessary to determine compliance with this chapter.

.06 Usage Requirements for Remote Automated Medication Systems.

A. A remote automated medication system may only be used if:

(1) Records concerning transactions or operations are maintained in accordance with Regulation .11 of this chapter;

(2) A responsible pharmacist has been designated by the permit holder to supervise and manage the operations of the remote automated medication system;

(3) Except for starter doses, a licensed pharmacist reviews each order for medication:

(a) After the order has been entered into the system; and

(b) Before the system permits access to the medication;

(4) The permit holder ensures that:

(a) Patients have prompt access to pharmacy services necessary for the provision of good pharmaceutical care as defined in Health Occupations Article, §12-101, Annotated Code of Maryland;

(b) The remote automated medication system maintains the integrity of the information in the system and protects patient confidentiality; and

(c) The remote automated medication system is subject to a quality assurance program in accordance with Regulation .10 of this chapter; and

(5) It is designed to distribute medications in a licensed health care facility, a related institution as defined in Health-General Article, §19-301, Annotated Code of Maryland, or a medical facility owned and operated by a group model health maintenance organization as defined in Health-General Article, §19-713.6, Annotated Code of Maryland.

B. A starter dose, or a dose in response to an emergency, may be distributed without prior review by a pharmacist of the order if the pharmacist reviews the order within 24 hours of removal from the remote automated medication system.

C. If a licensed pharmacist is not physically present where the remote automated medication system is located, the pharmacist shall have access to the system by electronic and visual means in order to ensure the safe and efficient operation of the system.

D. Remote automated medication systems shall operate in a manner which:

(1) Unless packaging and labeling for a specific patient, limits simultaneous access to multiple:

(a) Drug strengths;

(b) Dosage forms; or

(c) Drug entities;

(2) Prevents access to medication not ordered for the patient; and

(3) Safeguards against the misidentification of medications, dosages, and dosage forms by those accessing the remote automated medication system.

E. The requirements listed in §D(1) and (2) of this regulation do not apply to automated supply towers which contain:

(1) Noncontrolled medications that are:

(a) Refrigerated;

(b) Bulk; or

(c) Intravenous fluids; or

(2) Prescription devices.

F. A remote automated medication system may be used only if the system:

(1) Uses positive drug identification, such as bar code technology, to ensure accuracy in:

(a) Loading and selection of medications in the pharmacy for stocking and replenishment of the remote automated medication system; and

(b) Loading medications into the remote automated medication system where it is located;

(2) Has electronic reporting capability regarding the identity of persons with access to the system and regarding medications removed from the system;

(3) Restricts access to medications to a licensed pharmacist or an individual authorized to administer medication under Health Occupation Article, Annotated Code of Maryland; and

(4) Before administration of a medication to a patient, provides:

(a) A picture of the medication, if available; or

(b) If a picture is not available, a written description of the medication specifically by color, shape, and unique manufacturer markings.

G. The permit holder shall ensure that the health care facility where the remote automated medication system is located provides, at a minimum:

(1) A licensed pharmacist available for consultation 24 hours per day;

(2) Technical assistance regarding operation of the system available 24 hours per day; and

(3) A quality assurance program as set forth in Regulation .10 of this chapter.

H. A permit holder shall indicate on the initial, renewal, and reinstatement applications:

(1) Whether the permit holder operated a remote automated medication system; and

(2) Any other information regarding the system that the Board considers necessary to determine compliance with this chapter.

.07 Stocking of Automated Medication Systems.

A. Selection of Medication for Stocking. A licensed pharmacist shall verify the accuracy of medications selected for stocking and replenishment of the automated medication system before the medications are stocked in the system.

B. Stocking of Automated Medication System. A registered pharmacy technician may stock an automated medication system provided that:

(1) The pharmacy technician's selection of medications is verified by a pharmacist; and

(2) The system uses positive drug identification such as bar code technology.

.08 Return of Unused Medication.

A. Single-Drug Unit Dose Packaging.

(1) Automated medication systems that distribute medications in single-drug unit dose packaging may allow for return of unused medications to the system provided that:

(a) The medication is returned to a designated common, secure, one-way returns bin; and

(b) A licensed pharmacist determines whether the medication is in an unadulterated form.

(2) Only a licensed pharmacist may return medications directly to the automated medication system under §A(1) of this regulation.

B. Unused medications distributed from a remote or decentralized automated medication system in a manner other than single-drug unit dose packaging shall be:

(1) Returned to a designated common, secure, one-way returns bin; and

(2) Returned to the permit holder for proper disposal.

C. Unused medications dispensed from a centralized automated medication system stocked with bulk medications may not be returned to the system.

.09 Education and Training.

The permit holder shall ensure that individuals authorized to utilize centralized, decentralized, or remote automated medication systems receive initial and annual training regarding:

A. The capabilities and limitations of the system;

B. Procedures for the operation of the system; and

C. Procedures for system downtime.

.10 Quality Assurance Program.

A. The responsible pharmacist, in consultation with the health care facility, a related institution as defined in Health-General Article, §19-301, Annotated Code of Maryland, or a medical facility owned and operated by a group model health maintenance organization as defined in Health-General Article, §19.713.6, Annotated Code of Maryland, shall develop, maintain, and review annually a quality assurance program regarding the automated medication system that addresses, at minimum:

(1) A testing program which includes daily accuracy sampling that verifies the integrity of the system;

(2) Investigation of medication errors related to the automated medication system, and remedial actions taken;

(3) Review of discrepancies and transaction reports to identify patterns of inappropriate use and access;

(4) Review of the overall functioning of the system2;

(5) Security and access:

(6) Preventative maintenance;

(7) Sanitation;

(8) Storage conditions;

(9) Inventory of drugs;

(10) Drug procurement, delivery, and receipt;

(11) Record keeping;

(12) Proper labeling procedures; and

(13) Protocols in the event of a power outage or other situation in which the services of the system are interrupted, that include:

(a) A plan for insuring continuity of pharmacy services to patients; and

(b) A plan for system recovery.

B. The responsible pharmacist, in consultation with the health care facility, a related institution as defined in Health-General Article, §19-301, Annotated Code of Maryland, or a medical facility owned and operated by a group model health maintenance organization as defined in Health-General Article, §19.713.6, Annotated Code of Maryland, shall develop, maintain, and review annually a quality assurance program regarding the remote or decentralized automated medication system that addresses, at a minimum, system override management to include:

(1) A list of medications that can be overridden which is limited to starter doses; and

(2) Review of system overrides to ensure appropriate utilization.

.11 Record Keeping.

A. The permit holder and the responsible pharmacist shall maintain records regarding the automated medication system in a readily retrievable manner for at least 5 years.

B. The records referred to in §A of this regulation shall include:

(1) Maintenance records and service logs;

(2) System failure reports;

(3) Documentation of patient outcomes resulting from system failures;

(4) Accuracy audits and system performance audits;

(5) Copies of reports and analyses generated as part of the quality assurance program, including daily accuracy sampling;

(6) Reports or databases related to level of access and changes in the level of access to the system;

(7) Training records including:

(a) Contents of the training program;

(b) Dates of training completion; and

(c) The identity of those attending the training program;

(8) Records of destruction of medication waste removed from the system, to include an independent witness signature; and

(9) Transaction information as follows:

(a) Transactions involving medications stored in or removed, dispensed, or distributed from the system;

(b) Medications dispensed or distributed for a patient, which shall be recorded to include the:

(i) Identity of the particular automated medication system accessed;

(ii) Identification of the individual accessing the system;

(iii) Date of transaction;

(iv) Name, strength, dosage form, and quantity of drug accessed; and

(v) Name of the patient for whom the drug was accessed; and

(c) Records of stocking or removal of medications from an automated medication system, which shall include the:

(i) Date;

(ii) Name, strength, dosage form, and quantity of drug stocked or removed; and

(iii) Name, initials, or identification code of the individual stocking or removing drugs from the system.

.12 Security.

A. The responsible pharmacist shall ensure the security of the automated medication system.

B. In order to restrict access to the automated medication system to authorized individuals, the responsible pharmacist shall, at a minimum:

(1) Establish a clear process of how passwords will be assigned;

(2) Develop procedures that prohibit the sharing of passwords and reuse of passwords;

(3) Require that the system database be updated daily to remove inactive passwords; and

(4) Require remote locking mechanisms for refrigerated storage associated with the system.

.13 Laws and Compendial Standards.

The responsible pharmacist shall ensure compliance with the laws and compendial standards for packaging and labeling.

.14 Controlled Dangerous Substances.

Controlled dangerous substances shall only be dispensed and distributed in accordance with applicable State and federal statutes and regulations.