

480-37, Remote Automated Medication Systems in the State of Georgia.

480-37-.01 Definitions

For purposes of this Chapter, the following words shall mean:

- (a) “Board” means the Georgia Board of Pharmacy
- (b) “GDNA” means the Georgia Drugs and Narcotics Agency.
- (c) “Remote automated medication system” or “RAMS” means an automated mechanical system in which medication is stored and retrieved for a specific patient pursuant to a practitioner’s prescription medication order.

Authority: O.C.G.A. Sections 26-4-5 and 26-4-28.

480-37-.02 Licensure

- (a) In order to install or operate a RAMS, a Georgia licensed pharmacy must make application for licensure to the Board on a form approved by the Board, and pay a fee. No person other than an approved licensed pharmacy may install or operate a RAMS. Each location having a RAMS must have a separate license from the Board. If more than one licensed pharmacy operates a RAMS at the same skilled nursing facility or hospice, each licensed pharmacy must maintain a registration at the skilled nursing facility or hospice. A Georgia licensed pharmacy that has paid a fee for one RAMS location will not be required to pay fees for the additional locations.
- (b) A Georgia licensed pharmacy may only use the RAMS at a skilled nursing facility or hospice licensed as such pursuant to O.C.G.A. T. 31, Ch. 7, that does not have an on-site licensed pharmacy.
- (c) The Pharmacist-in-Charge (PIC) for a licensed pharmacy shall be considered the PIC for each separate license to operate a RAMS at a skilled nursing facility or hospice.
- (d) The RAMS must collect, control, and maintain all transaction information.

Authority: O.C.G.A. Sections 26-4-5, 26-4-28 and 26-4-110.

480-37-.03 Minimum Requirements

Minimum Requirements. A pharmacy may use a RAMS provided that:

- (a) The pharmacy has a policy and procedure manual at the skilled nursing facility or hospice that includes:
 - 1) The type or name of each RAMS including a serial number or other identifying nomenclature.
 - 2) A method to ensure security of a RAMS to prevent unauthorized access. Such method may include the use of electronic passwords, biometric identification (optic scanning or fingerprint) or other coded identification.
 - 3) A process of filling and stocking a RAMS with drugs; an electronic or hard copy record of medication filled into the system including the product identification, lot number, and expiration date.
 - 4) Documentation of inventory procedures including removal of any discontinued/out-dated medications.
 - 5) Compliance with a Continuous Quality Improvement Program.

- 6) A method to ensure that patient confidentiality is maintained.
- (b) No more than a 30 day supply of each individual medication may be stocked in a RAMS at one time.
- (c) All drugs in a RAMS must inventoried no less than once every 30 days and documentation must be maintained of the inventories including the removal of any discontinued/out of date medications.
- (d) All the registered pharmacists, licensed pharmacy interns or registered pharmacy technicians involved in the process of stocking, entering information into RAMS, or inventorying the RAMS must be identified. No person shall be permitted to perform a function related to the machine that they are not authorized to do in the pharmacy. Specifically, where direct supervision is required in the pharmacy, such supervision must occur in duties related to the RAMS.
- (e) Patient confidentiality must be maintained.
- (f) The PIC, or a pharmacist designated by the PIC, must be able to revoke, add, or change access to RAMS at any time.
- (g) Only a Georgia registered nurses or a Georgia licensed practical nurse may be assigned access to and remove dangerous drugs from a RAMS.
- (h) Only a Georgia registered nurse may access and remove a controlled substances from a RAMS
- (i) The system ensures that each prescription is dispensed in compliance with the definition of dispense and the practice of the profession of pharmacy.
- (j) The system shall maintain a readily retrievable electronic record to identify all pharmacists, pharmacy interns, or registered pharmacy technicians involved in the processing of the prescription order.
- (k) A RAMS shall provide the ability to comply with product recalls generated by the manufacturer, distributor, or pharmacy. The system shall have a process in place to isolate affected lot numbers including an intermix of drug product lot numbers.
- (l) The stocking or restocking of a dangerous drug or controlled substances shall only be completed by a Georgia pharmacist or a pharmacy intern/extern under the direct on-site supervision of a Georgia licensed pharmacist.
- (m) A RAMS must use at least two separate verifications, such as bar code verification, electronic verification, weight verification, radio frequency identification (RFID) or similar process to ensure that the proper medication is being dispensed from a RAMS.
- (o) All medication shall be packaged and labeled in compliance with Board rules and laws for patient specific labeled medication and/or unit of use medication.
- (p) The licensed pharmacist responsible for filling, verifying, or loading the RAMS shall be responsible for their individual action.
- (q) A prescription drug dispensed by the RAM pursuant to the requirements of this rule shall be deemed to have been certified by the pharmacist.
- (r) A licensed pharmacist may remove discontinued and/or out-dated medications from the RAMS and return such medications to the licensed pharmacy for proper disposition. A registered or licensed practical nurse may remove discontinued and/or out-dated medications and place them in the designated secured return bin in a RAMS.

Authority: O.C.G.A. Sections 26-4-5, 26-4-28, 26-4-80, 26-4-82 and 26-4-110.

480-37-.04 Dispensing of Drugs.

Drugs shall only be dispensed by the RAMS pursuant to prescription drug orders of practitioners authorized under the laws of this state to prescribe drugs.

Authority: O.C.G.A. Sections 16-13-41, 16-13-74, 26-4-5, and 26-4-28.

480-37-.05 Inspections

(1) The Pharmacist in Charge, personally or by licensed pharmacist designee, shall inspect all RAMS within his/her jurisdiction and responsibility and make appropriate written records of such inspections. Such inspections, at a minimum, shall verify that:

- a) All drugs in a RAMS must inventoried no less than once every 30 days. All controlled substances drugs in a RAMS must inventoried no less than once every 7 days. A system of accountability must exist for all drugs contained in a RAMS.
- (b) Drugs requiring special storage conditions are properly stored to insure their stability;
- (c) No outdated drugs are stocked in a RAMS;
- (d) Distribution and administration of controlled substances are properly and adequately documented and reported by both pharmacy and other licensed medical personnel;
- (e) Only medications may be stored in a RAMS and all medications stored in the RAMS must be on the RAMS inventory list.
- (f) All necessary and required security and storage standards are met;
- (g) A licensed pharmacist will empty the return bin at least every 30 days. Discontinued/outdated return transactions shall be documented by the RAMS.

(2) Board of Pharmacy shall be conducted by representatives of the GDNA. Such inspections shall include all aspects of the management and operation of all RAMS in this State to verify compliance with the Pharmacy Laws, the Rules and Regulations of the Board of Pharmacy, and such other standards as may be appropriate to insure that the health, safety, and welfare of patients of the skilled nursing facility and/or hospice are protected. A written report shall be filed with the GDNA, the licensed pharmacy, and skilled nursing facility or hospice. Any discrepancies or deficiencies noted shall be corrected and written notice filed with GDNA within 30 days after receipt of the inspection notice.

Authority: O.C.G.A. Sections 26-4-5, 26-4-28 and 26-4-29.