

CHAPTER 9  
AUTOMATED MEDICATION DISTRIBUTION SYSTEMS

**657—9.1(79GA,ch182) Definitions.** For the purposes of this chapter, the following definitions shall apply:

“*Automated medication distribution system*” or “*AMDS*” includes, but is not limited to, mechanical or electronic systems that perform operations or activities relative to the storing, packaging, compounding, labeling, dispensing, administering, or distributing of medications and which collect, control, and maintain all transaction information.

“*Board*” means the board of pharmacy examiners.

“*Centralized unit dose AMDS*” means an AMDS located in the pharmacy where automated technology is utilized in the dispensing of patient-specific unit dose medications.

“*Component*” means any single physical or electronic storage or access device that, in combination with other devices, makes up the AMDS.

“*Decentralized unit dose AMDS*” means an AMDS where automated technology is utilized in the dispensing of unit dose medications and medication-dispensing components are maintained in remote locations.

“*Emergency medications*” means those medications critical for patient care and approved by the institution’s pharmacy and therapeutics committee or equivalent committee. Medications critical for patient care include medications requiring administration within minutes or within less time than the pharmacy can be practically expected to respond, such as the administration of naloxone for treatment of an opioid overdose.

“*Floor-stock medications*” means those medications consisting of emergency medications and controlled substances which are routinely maintained on patient care units and accessible by nursing staff for patient administration.

“*Information access*” means the entry into a record-keeping component of the AMDS, by electronic or other means, for the purpose of adding, updating, or retrieving any patient record or medication record or data.

“*Medication access*” means the physical entry into any component of the AMDS for the purpose of stocking or removing medications.

“*Medication bin*” means a compartment in an AMDS component that is designed to contain one specific medication.

“*Outpatient AMDS*” means an AMDS where automated technology is utilized in the dispensing of prescriptions for ambulatory patients.

“*Remote location*” means any location outside the licensed pharmacy where any component of an AMDS is located and includes the following:

1. Patient care areas or medication rooms in a hospital, skilled nursing facility, or long-term care facility.
2. Ambulatory care or surgery centers.
3. Clinics and health practitioners’ offices.
4. Other locations approved by the board.

**657—9.2(79GA,ch182) Pharmacist in charge responsibilities.** The pharmacist in charge shall be responsible for the following:

1. Implementing an ongoing quality assurance program that monitors and strives to improve performance of each AMDS.
2. Establishing and ensuring compliance with all policies and procedures relating to the AMDS.
3. Assigning, discontinuing, or changing medication and information access to the AMDS.
4. Ensuring that medication access, including access to controlled substances, complies with state and federal regulations.
5. Ensuring that each AMDS is filled or stocked accurately and in accordance with established, written policies and procedures.
6. Ensuring that each AMDS is in good working order and performs its designated tasks, including ensuring the correct strength, dosage form, and quantity of the prescribed medication.
7. Ensuring that the AMDS has adequate security safeguards regarding medication access and information access.
8. Ensuring that confidentiality of patient-specific information is maintained.
9. Ensuring that all personnel utilizing or accessing the AMDS have been appropriately trained.
10. Ensuring that the board is provided with written notice at least 30 days prior to an installation, removal, or upgrade that significantly changes the operation of an AMDS. The notice shall include:
  - The name, address, and license number of the pharmacy;
  - The location of the automated equipment;
  - Identification of the pharmacist in charge;
  - The name, manufacturer, and model of the system;
  - A description of the change or upgrade, if applicable; and
  - If installing a new or significantly changed AMDS, a copy of the quality assurance plan when applicable.

**657—9.3(79GA,ch182) Quality assurance and performance improvement.** The goal of AMDS is the accurate dispensing of medications. In all dispensing activities, the pharmacy shall strive for 100 percent accuracy.

**9.3(1) *Quality assurance.*** Pharmacies shall develop a quality assurance and monitoring plan prior to implementation of the AMDS. The quality assurance plan shall target the preparation, delivery, and verification of AMDS unit contents during fill and refill processes.

**9.3(2) *Performance improvement.*** Performance improvement projects shall utilize quality assurance data to monitor and improve systems.

**9.3(3) *Records.*** All records and documentation of quality assurance and monitoring and performance improvement projects shall be maintained by the pharmacy and be available for inspection and copying by the board or its representative for a minimum of two years from the date of the record.

**657—9.4(79GA,ch182) Policies and procedures.** All policies and procedures shall be written and shall be maintained in the pharmacy responsible for the AMDS. All pharmacies utilizing AMDS shall develop, implement, and adhere to policies and procedures that address, at a minimum, the following:

1. Type of equipment, system components, and location including:
  - Name and address of the pharmacy or remote location where any component of the AMDS is being used, and
  - Manufacturer's name and model of each system component.
2. Medication access and information access procedures.

3. Security and confidentiality of records in compliance with 657—8.16(124,155A) and 657—21.2(124,155A).
4. Description of how the component is being utilized including processes for dispensing and distributing medications.
5. Staff education and training.
6. Review, including prospective drug use review, of medication orders and prescriptions in accordance with federal and state laws and regulations.
7. Patient counseling on outpatient prescriptions.
8. Quality assurance and quality improvement.
9. Downtime procedures.
10. Periodic system maintenance.
11. Medication security and control including:
  - Medication loading, storage, and records.
  - Medications removed but not used.
  - Inventory.
  - Cross contamination.
  - Lot number control.
  - Wasted or discarded medications.
  - Controlled substances.

**657—9.5(79GA,ch182) System, site, and process requirements.** An AMDS may be utilized on site by licensed pharmacies or in remote locations as defined in rule 9.1(79GA,ch182). Each AMDS shall comply with the following minimum requirements:

**9.5(1) System access.**

- a.* The AMDS shall automatically and electronically record medication access.
- b.* Medication access and information access records shall include, at a minimum, the date the AMDS was accessed, the identity of the individual who accessed the system, the type of transaction completed, and the identity of the accessed component.
- c.* Information access for the purpose of retrieving or reviewing any patient or medication record or data, when the access does not permit change or addition to the record or data, shall be exempt from the access record requirements of paragraph “*b*” of this subrule.
- d.* The AMDS shall include the ability to assign, discontinue, and change medication access and information access to the AMDS.
- e.* A licensed pharmacist or appropriately trained pharmacy technician under the oversight of a licensed pharmacist shall fill and stock medications in the AMDS.
- f.* A record of medications filled or stocked into an AMDS shall be maintained and shall include identification of the person filling or stocking the system and, if applicable, the person checking for accuracy.

**9.5(2) Dispensing and distributing.**

- a.* All containers of medications stored in each AMDS shall be packaged and labeled in compliance with federal and state laws and regulations.
- b.* All aspects of handling controlled substances shall comply with the requirements of all state and federal laws and regulations.

c. Each AMDS shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the system. Medications removed from a system component but not administered to a patient shall be returned to the pharmacy or maintained in a manner that would prevent access to the returned medications except for the purpose of returning the medications to the pharmacy. The provisions of this paragraph regarding preventing access to returned medications except for return to the pharmacy shall not apply to items that are too large or bulky to be inserted into the system's return bin, to items requiring refrigeration, nor to limited critical care items whose inaccessibility would compromise patient care.

d. Each AMDS shall provide a mechanism for securing and accounting for wasted or discarded medications in compliance with federal and state laws and regulations.

**9.5(3) Security and confidentiality.** An AMDS shall include system safeguards designed to prevent and detect unauthorized medication access, including access to controlled substances. System safeguards shall also be designed to prevent and detect unauthorized information access for the purpose of modification or manipulation of patient records and prescription drug orders.

a. An AMDS shall be capable of generating reports of all medication access activity. Reports shall include, at a minimum for each medication access record, the following:

- (1) Identification of the person.
- (2) The date and, preferably, the time.
- (3) Identification of the medication.
- (4) Whether the medication access involved stocking, dispensing, wasting, or returning the medication.
- (5) The quantity of the medication.
- (6) The accessed component.

b. An AMDS shall maintain confidential patient records and information in compliance with rules 657—8.16(124,155A) and 657—21.2(124,155A).

**657—9.6(79GA,ch182) Records.** All records required pursuant to these rules shall be available to the board or its authorized agents for two years following the recorded activity.

**657—9.7(79GA,ch182) Decentralized unit dose AMDS.** Decentralized unit dose AMDS may be utilized in two ways. Either subrule 9.7(1) or subrule 9.7(2) shall apply, based on the utilization of the decentralized unit dose AMDS.

**9.7(1) Floor-stock distribution.** If the decentralized unit dose AMDS is utilized for the storage and dispensing of floor-stock medications only, medications may be restocked into components by an appropriately trained pharmacy technician following pharmacist verification in the pharmacy of medications to be restocked.

**9.7(2) Other than floor-stock distribution.** If the decentralized unit dose AMDS is utilized for medications other than floor-stock medications, including but not limited to medications intended for first-dose administration or medications otherwise dispensed in unit dose cassettes, the following shall apply:

a. *Pharmacist or nurse verification.* When bar coding or other technology-based verification is not utilized to check the accuracy of medication doses stocked in dispensing components, a pharmacist or a nurse shall verify that 100 percent of all medication doses are accurately placed in each medication bin of each dispensing component. Policies, procedures, and safeguards shall be developed and implemented that control, while ensuring availability and access to needed medications, utilization of medications added to the dispensing component prior to pharmacist or nurse verification of the addition. Policies and procedures shall also provide for documentation identifying the individual who provides verification of medications stocked in dispensing components.

*b. Bar coding or technology-based verification.* When bar coding or other technology-based verification is utilized and a pharmacist is not filling the dispensing component, the quality assurance plan shall provide for random verification by a pharmacist. The plan shall provide that, one day each month, all medication doses or bins contained in 5 percent of the components utilized within the system be verified by a pharmacist. Or the plan shall provide that, one day each month, 5 percent of the medication doses or bins contained in each component utilized within the system be verified by a pharmacist. If, however, the system includes fewer than five components, a pharmacist shall, one day each month, verify all medication doses or bins contained in one component utilized within the system. A pharmacy may petition the board pursuant to 657—Chapter 34 for a variance for an alternate pharmacist verification process.

**9.7(3) Errors identified.** All identified errors shall be logged as provided by the quality assurance and monitoring plan developed pursuant to rule 9.3(79GA,ch182) and shall be categorized as follows:

1. Incorrect medication;
2. Incorrect dose;
3. Incorrect dosage form;
4. Other errors. All errors categorized as “other errors” shall include additional notation identifying the error.

**657—9.8(79GA,ch182) Centralized unit dose AMDS.** The quality assurance plan shall provide for pharmacist verification of all medication doses dispensed for a minimum of 60 days following implementation of the AMDS.

**9.8(1) Errors logged.** All identified errors shall be logged as provided by the quality assurance and monitoring plan developed pursuant to rule 9.3(79GA,ch182) and shall be categorized as follows:

1. Computer order entry error;
2. Incorrect medication;
3. Incorrect dose;
4. Incorrect quantity—extra dose(s);
5. Incorrect quantity—short dose(s);
6. Incorrect dosage form;
7. Other errors. All errors categorized as “other errors” shall include additional notation identifying the error.

**9.8(2) Initial report to the board.** The first quarterly report to the board shall summarize identified errors by category and shall include the total number of errors identified, the reasons for the errors, the corrective actions taken to prevent the recurrence of those errors, and the average accuracy (correct doses over total doses) determined for all AMDS-dispensed medications during the first quarter following implementation.

**9.8(3) Random verification.** If the average accuracy of the AMDS during the initial 60-day period is at least 99.7 percent for all medication doses dispensed, the quality assurance plan shall provide for random verification by a pharmacist. The plan shall provide that 5 percent of all medication doses daily dispensed utilizing the AMDS be verified by a pharmacist or it shall provide that 100 percent of all medication doses dispensed on a specific day each month be verified by a pharmacist. A pharmacy may petition the board pursuant to 657—Chapter 34 for a variance for an alternate pharmacist verification process. Errors shall continue to be identified and logged as provided by the quality assurance and monitoring plan developed pursuant to rule 9.3(79GA,ch182) and shall be categorized as provided in subrule 9.8(1).

If the average accuracy of the AMDS during the initial 60-day period is not at least 99.7 percent for all medication doses dispensed, the pharmacy shall continue pharmacist verification of all medication doses dispensed utilizing the AMDS until the average accuracy for 60 consecutive days is at least 99.7 percent.

**9.8(4) Reports during first year.** For a minimum of one year following implementation of the AMDS, written quarterly reports shall be submitted to the board. Reports shall summarize identified errors by category and shall include the total number of errors identified, the reasons for the errors, the corrective actions taken to prevent the recurrence of those errors, and the average accuracy (correct doses over total verified doses) for all medication doses verified during the preceding quarter.

**9.8(5) Accuracy.** Any random verification disclosing accuracy of less than 99.7 percent for all medication doses verified shall require that a pharmacist again verify all medication doses dispensed utilizing the AMDS until the average accuracy meets or exceeds 99.7 percent for all medication doses dispensed for three consecutive days.

**9.8(6) Continued verification.** The quality assurance plan shall provide for continuation, as long as the pharmacy utilizes the AMDS, of random verification by the pharmacist of AMDS-dispensed medication doses as provided in subrules 9.8(3) and 9.8(5).

**9.8(7) Reports after one year.** Following the one-year period and within 30 days of determining by random verification that the accuracy of AMDS medication fills is less than 99.7 percent for all medication doses verified, a written report shall be submitted to the board. The report shall summarize the identified errors by category and shall include the reasons for the errors, the corrective actions taken to prevent the recurrence of those errors, and the low accuracy rate prompting the report.

### **657—9.9(79GA,ch182) Outpatient AMDS.**

**9.9(1) Verification.** Prior to dispensing, all outpatient prescriptions dispensed utilizing an AMDS shall be verified by a pharmacist in the pharmacist's physical presence unless a waiver is approved pursuant to subrule 9.9(2).

**9.9(2) Waiver.** A pharmacy may request waiver or variance from subrule 9.9(1) pursuant to the procedures and requirements of 657—Chapter 34. In addition, applications for waiver shall specify and include justification for the requested waiver, the methods to be used to ensure patient counseling is provided on new prescriptions pursuant to 657—8.20(155A), a quality assurance plan, and written policies and procedures for utilization of the AMDS.

*a. Quarterly reports.* The quality assurance plan shall provide for submission of written quarterly reports to the board. All reports shall summarize identified errors by category and shall include reasons for the errors, the corrective actions taken to resolve and prevent recurrence of the errors, and average accuracy for the specified period.

*b. Verification.* The quality assurance plan shall provide for verification processes for all AMDS-dispensed prescriptions.

*c. Identification of errors.* The quality assurance plan shall require that all identified errors be logged as provided by the quality assurance and monitoring plan developed pursuant to rule 9.3(79GA,ch182) and shall be categorized as follows:

1. Incorrect medication;
2. Incorrect quantity;
3. Incorrect dose;
4. Incorrect dosage form;
5. Incorrect directions for use;
6. Incorrect patient name;
7. Other incorrect label information;
8. Computer order entry error;
9. Other errors. All errors categorized as "other errors" shall include additional notation identifying the error.

*d. Accuracy.* The performance improvement plan shall identify actions to be taken in the event that any medication error is identified.

These rules are intended to implement 2001 Iowa Acts, chapter 182, section 5(10), paragraph “i.”

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