

657—21.10(124,155A) Automated medication distribution system (AMDS). Any pharmacy that utilizes an AMDS shall comply with these rules in addition to all applicable federal and state laws, rules, and regulations.

21.10(1) Policies and procedures. Pursuant to the requirements regarding policies and procedures in 657—subrule 8.3(5), each pharmacy utilizing an AMDS shall have policies and procedures that address all aspects of the operation of the AMDS to include, at a minimum:

- a. Access to drugs and patient information,
- b. Pharmacy personnel training in the proper operation of the AMDS,
- c. Methods to ensure accurate stocking of the AMDS pursuant to subrule 21.10(2),
- d. Confidentiality of patient information,
- e. Routine and preventative maintenance of the AMDS according to manufacturer recommendations,
- f. Packaging and labeling of prescription drugs loaded into or dispensed from the AMDS that is in compliance with federal and state laws, rules, and regulations, and
- g. Security and control of the prescription drugs maintained and utilized in the AMDS to include:
 - (1) Drug loading, storage, and records.
 - (2) Drugs removed from system components but not used.
 - (3) Inventory.
 - (4) Cross contamination.
 - (5) Lot number control.
 - (6) Wasted or discarded drugs.
 - (7) Controlled substances.

21.10(2) Stocking the AMDS. The pharmacy shall have adequate procedures in place to ensure the accurate stocking of drugs into an AMDS using barcode scanning technology. Only a pharmacy technician, pharmacist-intern, or pharmacist shall be allowed to participate in the stocking of the AMDS.

21.10(3) Pharmacist verification of drugs dispensed from AMDS.

a. When an AMDS only dispenses drugs that were prepackaged and verified by a pharmacist prior to being stocked in the AMDS and there was no further manipulation of the drug or package other than affixing a patient-specific label, such drugs shall not require additional pharmacist verification prior to administration or dispensing to the patient or authorized representative.

b. When a drug is stocked in an AMDS and undergoes further manipulation, such as counting and packaging, such drugs shall require pharmacist verification prior to dispensing to the patient. Such verification shall be documented.

21.10(4) Placement of AMDS.

a. An AMDS placed outside a pharmacist's direct supervision shall only dispense pharmacist-verified packages in compliance with paragraph 21.10(3) "a."

b. An AMDS that manipulates, including but not limited to counting, packaging, or labeling, prescription drugs for subsequent patient dispensing shall only be utilized in a pharmacy under the direct supervision of a pharmacist, except in an approved telepharmacy pursuant to 657—Chapter 13.

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