657—9.11 (147,155A) Policies and procedures. Notwithstanding rule 657—8.3(155A), policies and procedures for an AMDS shall be required pursuant to this chapter. All policies and procedures shall be in writing and shall be maintained in the pharmacy responsible for the AMDS or, if a telepharmacy practice, shall be maintained at both the managing pharmacy and the remote site. All policies and procedures shall be reviewed at least annually and revised as necessary, and the review shall be documented. Additions, deletions, amendments, and other changes to policies and procedures shall be signed or initialed by the pharmacist in charge, shall include the date on which the change was approved, and shall be maintained for a minimum of two years following the date of the change. The policy and procedure manual and retained changes shall be available for inspection and copying by the board or an agent of the board.

9.11(1) *AMDS.* Pursuant to rule 657—8.3(155A) and this chapter, a pharmacy shall have policies and procedures for an AMDS that provide, at a minimum, the following:

a. Type of equipment, system components, and location of each system component including:

(1) Name and address of the pharmacy, including identification of the specific location within an institution but outside the pharmacy where any component of the AMDS is being used;

(2) Name and address of any remote dispensing site where a component of the AMDS is being used; and

(3) Manufacturer's name and model of each system component.

b. Drug access and information access procedures.

c. Security and confidentiality of records in compliance with 657—8.16(124,155A) and 657—21.2(124,155A).

d. Description of how each component is being utilized, including processes for dispensing and distributing drugs.

e. Staff education and training.

f. Review, including prospective drug use review, of medication orders and prescriptions in accordance with federal and state laws and regulations.

g. Patient counseling on outpatient prescriptions.

h. Quality assurance and quality improvement.

i. Downtime or system failure procedures.

j. Periodic system maintenance and preventive maintenance.

k. Drug security and control including:

(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.

9.11(2) *Telepharmacy.* In addition to other requirements for policies and procedures relating to pharmacy practices and the requirements of subrule 9.11(1) relating to policies and procedures for utilization of the AMDS, pharmacies engaging in telepharmacy shall develop, implement, and adhere to policies and procedures that address, at a minimum, the following:

a. Security, including identification by name of the personnel designated by the pharmacist in charge to have access to drug storage and dispensing areas at the remote dispensing site and to receive drugs delivered to the remote dispensing site.

b. Operation of the automated pharmacy system, including identification by name of the personnel designated by the pharmacist in charge to operate the system from the remote site or from the managing pharmacy, and identification by name of the individuals responsible for daily and periodic testing of the automated pharmacy system.

c. Identification of duties that may be performed only by a pharmacist.

d. Sanitation.

e. Storage of drugs and devices at the remote site.

f. Dispensing and delivery of drugs and devices from the remote site.

g. Supervision of remote site personnel.

h. Procurement, receipt, and delivery of drugs and devices to the remote site and into AMDS components.

i. Records.

j. Monthly pharmacist inspection of the remote dispensing site, including documentation of inspection.

k. The frequency of review of the policy and procedure manual and required documentation of that periodic review.

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