

657—11.11 (124,147A,155A) Policies and procedures.

11.11(1) Each service program shall, jointly with the service director and the responsible individual, develop, implement, and adhere to written policies and procedures for the operation and management of the service program with respect to prescription drugs and devices. These policies and procedures shall be available for inspection and copying by the board or its representative. The policies and procedures shall be periodically reviewed by the responsible individual, the medical director, and the service director. Documentation of the review shall be maintained.

11.11(2) The policies and procedures shall address, at a minimum, the following:

- a.* Storage of drugs at the primary program site and any program substations including appropriate temperature and humidity controls and security.
- b.* Protocols for administration of drugs.
- c.* Administration of drugs outside the parameters of written protocols.
- d.* Record retention and format including:
 - (1) Ownership of drugs.
 - (2) Ordering of drugs and devices.
 - (3) Receipt of drugs and devices.
 - (4) Distribution or administration of drugs and devices.
 - (5) Inspections of the primary program site, program substations, and drug supplies.
 - (6) Inventories of controlled substances.
 - (7) Wastage resulting from the administration of a partial dose or supply of a drug.
 - (8) Drug or device returns.
- e.* Process for the return of drugs.
- f.* Out-of-date and adulterated drugs.
- g.* Drug and device recalls.

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