

CHAPTER 11
DRUGS IN EMERGENCY MEDICAL SERVICE PROGRAMS

[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 11]

657—11.1(124,147A,155A) Definitions. For the purpose of this chapter, the following definitions shall apply:

“*Ambulance service*” means any privately or publicly owned service program which utilizes ambulances in order to provide patient transportation and emergency medical care at the scene of an emergency or while en route to a hospital. An ambulance service may use first response or nontransport rescue vehicles to supplement ambulance vehicles.

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

“*Department*” means the Iowa department of public health.

“*Drug*” means a substance as defined in Iowa Code section 155A.3(13) or a device as defined in Iowa Code section 155A.3(10).

“*EMS*” means emergency medical services.

“*Emergency medical technician*” means any emergency medical technician or EMT as defined in 641—132.1(147A).

“*Medical director*” means any physician licensed under Iowa Code chapter 148, 150, or 150A who shall be responsible for overall medical direction of the service program and who holds a current course completion card in advance cardiac life support (ACLS).

“*Physician*” means any individual licensed under Iowa Code chapter 148, 150, or 150A.

“*Physician assistant*” means any individual licensed under Iowa Code chapter 148C.

“*Physician designee*” means any registered nurse licensed under Iowa Code chapter 152 who holds a current course completion card in advanced cardiac life support (ACLS). The physician designee may act as an intermediary for a supervising physician in directing the actions of advanced emergency medical care personnel in accordance with written policies and protocols.

“*Rescue service*” means any privately or publicly owned service program which does not provide patient transportation and utilizes only rescue or first response vehicles to provide emergency medical care at the scene of an emergency.

“*Responsible individual*” means, in a medical director-based service, the medical director for the service; in a pharmacy-based service, the pharmacist in charge of the base pharmacy.

“*Service*” or “*service program*” means any 24-hour advanced emergency medical care ambulance service, rescue, or first response service that has received authorization by the department.

“*Supervising physician*” means any physician licensed under Iowa Code chapter 148, 150, or 150A who holds a current course completion card in advanced cardiac life support (ACLS). The supervising physician is responsible for medical direction of advanced emergency medical care personnel when such personnel are providing advanced emergency medical care.

657—11.2(124,147A,155A) Ownership of drugs—options. Ownership of any and all drugs used by an emergency medical service shall be maintained under one of the following options:

11.2(1) Pharmacy-based services. Any and all drugs shall be provided by a licensed pharmacy. Under this arrangement, all drugs shall remain the property of the pharmacy. For purposes of this chapter and unless otherwise noted, the pharmacist in charge of the base pharmacy shall be the responsible individual for the service program.

a. A formal written agreement shall be made between the base pharmacy and the service establishing that the EMS is operating as an extension of the base pharmacy with respect to the drugs.

b. Pharmacies shall provide drugs limited to the drugs listed in the service program’s written protocols.

11.2(2) *Medical director-based services.* Any and all drugs shall be provided by the medical director. Under this arrangement, all drugs shall remain the property of the medical director. For purposes of this chapter and unless otherwise noted, the medical director shall be the responsible individual for the service program.

Whenever necessary and appropriate, the medical director may consult with a pharmacist in regard to all matters relating to the proper use, storage, and handling of drugs and intravenous infusion products which may be administered to patients of the service program.

657—11.3(124,147A,155A) General requirements.

11.3(1) *Exchange program.* Any pharmacy may replace drugs, including controlled substances, which have been administered to patients upon receipt of an order issued by a physician, physician assistant, or physician designee so authorized.

11.3(2) *Controlled substance prescribing.* Controlled substances shall be prescribed only by a person who is so authorized by state law.

11.3(3) *Controlled substance disposal or destruction.* The disposal or destruction of the unused portion of a controlled substance shall be documented in writing and signed by two emergency service program personnel. Outdated or unwanted controlled substances shall be returned to the service base for proper disposal or destruction.

11.3(4) *Administration of drugs and intravenous infusion products.* An emergency medical technician shall not administer a drug or intravenous infusion product without the verbal or written order of a physician, physician assistant, physician designee, or by written protocol. The service program's responsible individual shall be responsible for ensuring proper documentation of orders given and drugs administered.

11.3(5) *Drug control policies and procedures.* The service program's responsible individual shall be responsible for developing and implementing a written drug and intravenous infusion product safeguard and control policy for the service. The policy shall include, but not be limited to, procedures regarding the following:

- a. Controlled substances;
- b. Medication orders;
- c. Physician orders;
- d. Adverse drug and intravenous infusion product reaction reports;
- e. Drug and intravenous infusion product administration;
- f. Drug and intravenous infusion product defect reports;
- g. Drug and intravenous infusion product recalls;
- h. Outdated or unused drugs and intravenous infusion products;
- i. Verbal orders;
- j. Inventory control;
- k. Drug and intravenous infusion product security;
- l. Records;
- m. Drug and intravenous infusion product procurement, storage, and ownership;
- n. Inspections;
- o. Drug exchange programs.

657—11.4(124,147A,155A) Procurement and storage. The responsible individual for the service shall be responsible for the procurement and storage of drugs and intravenous infusion products for the service program.

11.4(1) All drugs and intravenous infusion products shall be stored at the proper temperatures as defined by the USP/NF.

11.4(2) Any drug or intravenous infusion product bearing an expiration date may not be administered after the expiration date.

11.4(3) Outdated drugs and intravenous infusion products shall be quarantined together until such time as the items can be lawfully disposed.

657—11.5(124,147A,155A) Records. Every inventory or other record required to be kept under Iowa Code chapter 124 or 155A and board rules shall be kept by the responsible individual for the service program and be available for inspection and copying by the board or its representative for at least two years from the date of such inventory or record.

657—11.6(124,147A,155A) Inspections.

11.6(1) The responsible individual for the service program shall ensure proper inspection of the drugs and intravenous infusion products used by the service on a periodic basis. Proof of periodic inspection shall be in writing and made available upon request of the board or department.

11.6(2) Drugs and intravenous infusion products used by the service program, as well as records maintained by the responsible individual or service program, shall be subject to inspection and audit by the board. They shall also be subject to inspection by the federal Drug Enforcement Administration.

657—11.7(124,147A,155A) Security and control. The responsible individual for the service program shall be responsible for developing and implementing policies and procedures for the security and control of the service program's drug and intravenous infusion products, including provisions for adequate safeguards against theft or diversion of dangerous drugs, controlled substances, and records for such drugs. The following conditions must be met to ensure appropriate control over drugs and intravenous infusion products.

11.7(1) Policies and procedures shall identify who will have access to the drugs and intravenous infusion products.

11.7(2) Drugs and intravenous products shall be secured at all times in a manner that limits access to authorized personnel only.

These rules are intended to implement Iowa Code chapter 147A.

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