

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 that utilizes ambulances in order to provide patient transportation and emergency medical services.

“*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).

“*Emergency medical care personnel*” or “*provider*” means an individual who has been trained to provide emergency and nonemergency medical care at the first-responder, EMT-basic, EMT-intermediate, EMT-paramedic, paramedic specialist level, or other certification levels adopted by rule by the department and who has been issued a certificate by the department.

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

“*EMS*” means emergency medical services.

“*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 has completed a medical director workshop, sponsored by the department, within one year of assuming duties.

“*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, or any physician assistant licensed under Iowa Code chapter 148C and approved by the board of physician assistant examiners. The physician designee acts as an intermediary for a supervising physician in accordance with written policies and protocols in directing the actions of emergency medical care personnel providing emergency medical services.

“*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 medical care ambulance service or nontransport service that has received authorization by the department.

“*Supervising physician*” means any physician licensed under Iowa Code chapter 148, 150, or 150A. The supervising physician is responsible for medical direction of emergency medical care personnel when such personnel are providing 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. The service contract may provide for payment by the service to the pharmacy of reasonable fees or charges for nonproduct pharmacy services.

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 the paramedic or paramedic specialist responsible for administration of the controlled substance and witnessed by one of the emergency service program personnel or a licensed health care professional. 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 appropriately certified EMS provider shall not administer a drug or intravenous infusion product without the verbal or written order of a physician, physician assistant, or 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 ensure that written drug and intravenous infusion product security and control policies and procedures are developed and implemented for the service. The policies and procedures shall address, but not be limited to, the following:

- a. Controlled substances;
- b. Medication orders;
- c. Adverse drug and intravenous infusion product reaction reports;
- d. Drug and intravenous infusion product administration;
- e. Drug and intravenous infusion product defect reports and product recalls;
- f. Outdated or unused drugs and intravenous infusion products and their timely disposal;
- g. Drug and intravenous infusion product inventory control and security;
- h. Record keeping;
- i. Drug and intravenous infusion product procurement, storage, and ownership;
- j. Inspections and frequency of inspections;
- k. 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) *Temperature.* All drugs and intravenous infusion products shall be stored at the proper temperatures as defined by the USP/NF.

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

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

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

657—11.6(124,147A,155A) Inspections.

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

11.6(2) Inspection by regulatory agencies. 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. Controlled substances and controlled substances records shall also be subject to inspection and audit by the federal Drug Enforcement Administration.

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

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

11.7(2) Limited access. Drugs and intravenous infusion 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 and Iowa Code sections 124.301 and 155A.13.

[Filed 5/25/79, Notice 4/4/79—published 6/13/79, effective 7/18/79]

[Filed emergency 1/21/88—published 2/10/88, effective 1/22/88]

[Filed 9/23/93, Notice 5/26/93—published 10/13/93, effective 11/17/93]

[Filed 6/24/94, Notice 4/13/94—published 7/20/94, effective 8/24/94]

[Filed 9/8/99, Notice 6/2/99—published 10/6/99, effective 11/10/99]

[Filed 8/14/02, Notice 6/12/02—published 9/4/02, effective 10/9/02]