



Iowa Department of Public Health
Bureau of Emergency and Trauma Services

EMS Pharmacy Guidance

PURPOSE:

To provide policy and procedure guidance to service programs that carry and administer prescription medications and controlled substances in order to maintain compliance with Iowa Code Chapters 657-10(124, 155A), 657-11(124, 155A) and 641-132(147A).

DEFINITIONS:

Iowa Code 657-10 – Controlled Substances: This chapter establishes the minimum standards for any activity that involves controlled substances.

Iowa Code 657-11 – Drugs in Emergency Medical Service Programs: This chapter establishes the minimum standards for any activity that involves drugs in Emergency Medical Service Programs.

Iowa Code 641-132 – Emergency Medical Services – Service Program Authorization: This chapter establishes the minimum standards for any activity that involves Emergency Medical Service Programs.

BACKGROUND:

Iowa Code 641-132.3(8) establishes that service programs that administer prescription medications, to include controlled substances, shall:

- a. Have written pharmacy agreements in accordance with the Iowa board of pharmacy’s 657—Chapter 11.
- b. Maintain all medications in accordance with the rules of the Iowa board of pharmacy’s 657—Chapters 10 and 11.
- c. Develop, maintain, and follow a written pharmacy policy.

POLICIES AND PROCEDURES:

Iowa Code 657-11.11(2) establishes that service programs shall 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. Policies and procedures shall be developed by the service director, medical director and the responsible pharmacy individual, shall be periodically reviewed, and shall identify the frequency of the review along with maintaining documentation of the review.

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 controls , temperature monitoring and response when drugs are exposed to extreme temperatures pursuant to rule 657—11.13(124,147A,155A).
- b. Storage of drugs at the primary program site and any program substations, including adequate security to prevent diversion and unauthorized access to drugs and records pursuant to rule 657—11.13.
- c. Protocols for administration of drugs pursuant to rule 657—11.14.
- d. Administration of drugs outside the parameters of written protocols pursuant to rule 657—11.15.
- e. Service program personnel matters including, but not limited to:
 - (1) Access to prescription drugs and records, identifying level of access based upon employee certification level and scope of practice.
 - (2) Authority to administer drugs based upon employee certification level and scope of practice.
 - (3) Authority to order, receive, and distribute prescription drugs and devices.
 - (4) Initial training and periodic review of the medication policies and procedures.
 - (5) Identification of registered nurses not employed by the service program who are authorized by the medical director pursuant to Iowa Code section 147A.12 and pursuant to rules of the board of nursing to provide emergency care under the service program’s protocol.



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- f. Process for the return of drugs pursuant to rule 657—11.22.
- g. Out-of-date and adulterated drugs pursuant to rule 657—11.23.
- h. Drug and device recalls pursuant to rule 657—11.24.
- i. Monthly inspections pursuant to rule 657—11.20.
- j. Record retention as described in rule 657—11.34 and other applicable rules of the board.

CONTROLLED SUBSTANCES ACT (CSA) REGISTRATION:

Iowa Code 657-11.3 establishes that any service program which intends to provide services in or into Iowa that include the administration of controlled substances, the responsible individual shall ensure that each primary program site, regardless of location, is registered with the board pursuant to this rule. The current registration certificate shall be available at the primary program site for inspection and copying by the board, its representative, or any other authorized individual. CSA registration is required for:

- a. Medical director-based service programs – CSA and DEA registrations shall be obtained for each primary program site in the name of the medical director and shall be obtained prior to the procurement of any controlled substances for use in the service program. A separate CSA registration shall also be obtained in the name of the service program, shall secondarily name the medical director, and shall be issued for the address of the service program’s primary program site.
- b. Pharmacy-based service programs – CSA registration shall be issued in the name of the service program and shall secondarily name the provider pharmacy. The CSA registration shall be issued for the address of the service program’s primary program site and shall identify the pharmacist in charge of the provider pharmacy as the individual responsible for the controlled substances at the service program. A pharmacy-based service program that is owned by and physically located at the same address as an Iowa-licensed and -registered hospital may, but is not required to, obtain a separate registration.
- c. Combination pharmacy-based and medical director-based service programs - In a service program that is a combination of pharmacy-based and medical director-based and both the pharmacy and medical director provide controlled substances, each provider of controlled substances shall maintain a CSA registration with the board. A medical director-based program shall also maintain a federal DEA registration.

For further information with regard to Controlled Substances Act Registration, please go to <https://pharmacy.iowa.gov/licensureregistration/controlled-substance-applications>.

For further information with regard to Iowa Code 657-10 (Controlled Substances), please go to <https://www.legis.iowa.gov/docs/iac/chapter/657.10.pdf>.

For further information with regard to Iowa Code 657-11 (Drugs in Emergency Medical Service Programs), please go to <https://www.legis.iowa.gov/docs/iac/chapter/657.11.pdf>.

To locate your counties Iowa Board of Pharmacy Compliance Officer, please go to <https://pharmacy.iowa.gov/contact-us/board-compliance-officers>.

For the Iowa Board of Pharmacy’s website, please go to <https://pharmacy.iowa.gov/>.