SAMPLE – SAMPLE – SAMPLE – SAMPLE – SAMPLE
It is not mandatory that you use this form. It is your responsibility to ensure that the language provided in this example is accurate for your services needs and in accordance with current Iowa Code.
Prior to implementing this policy, remove this header: Double-click to open, CTRL+A to highlight and hit DELETE. Double-click within the body of the document to close the header.

EMS SERVICE OR SYSTEM
MEDICAL DIRECTOR-BASED OPTION
AGREEMENT, POLICIES AND PROCEDURES

FOR PRESCRIPTION DRUGS AND CONTROLLED SUBSTANCES

Type or Print Name and Location of Service (Primary Site):

Type or Print Name and Location of any Satellite Services:

General Purpose:
To establish a medication program that meets or exceeds the requirements of 481 Iowa Administrative Code (IAC) Chapter 555, Standards—Drugs in Emergency Medical Services Programs, and 641 IAC Chapter 132, Emergency Medical Services—Service Program Authorization.

General Procedure:
The interaction of the physician medical director, pharmacist, service leadership and EMS providers is critical for the success of the medication program. All staff must understand their role, responsibilities and duties as part of the team. Every team member shall receive an initial orientation to this policy and be provided with an opportunity for input and updates when amended.

CSA Registration:
In accordance with 481 IAC 555.2 and 551.11, service programs that administer controlled substances shall ensure that each primary program site is registered with the Iowa Board of Pharmacy.

Approval & Affirmation:
The signatures within this document indicate approval of the policies and procedures and commitment to perform the assigned duties as described within the agreement.

PRINT OR TYPE MEDICAL DIRECTOR INFORMATION:			
Name:	Street Address or PO Box:		City State, Zip Code
Day Phone Number:	Email Address:		
License Number	License Expiration	DEA Number	DEA Expiration

Policy Approval	**TYPE or Print Name**	**Signature**	**Date**
Medical Director			
Service Director at the Primary Site			

List the drugs that will be owned by the Medical Director:

SAMPLE – SAMPLE – SAMPLE – SAMPLE – SAMPLE
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*****Email a signed electronic copy or mail a copy of this signed policy to your Regional EMS Coordinator*****

SECTION A: RESPONSIBILITY, WRITTEN AGREEMENT, OWNERSHIP

Policy: The service shall maintain a formal written agreement and policies and procedures that describe the role and responsibilities of the parties that enter the agreement.

Procedure:

1. The medical director shall maintain ownership of the drugs used by the service program.

2. The medical director shall be responsible for ensuring that the management of all prescription drugs complies with federal and state laws and regulations.

3. The written agreement shall be signed by the medical director and service director and maintained at the primary site.

4. The service shall email an electronic copy or mail a copy of the signed agreement to the Regional EMS Coordinator promptly when initiated or amended.

SECTION B: TERMINATION OF SERVICES

Policy: This agreement may be terminated at the discretion of the medical director or service director.

Procedure:

1. Written notification of termination shall be provided to the other party at least 30 days prior to termination of services.

2. Immediately upon termination, all controlled substances shall be jointly inventoried by the medical director and the service director.

3. A record of the controlled substance inventory shall be maintained by the medical director and shall be readily retrievable and available for inspection and copying by the Iowa Board of Pharmacy or the Bureau of Emergency and Trauma Services.

4. All drugs that are the property of the medical director shall be immediately returned to the medical director.

SECTION C: REGISTRATION & CHANGE OF ADDRESS OF MEDICAL DIRECTOR

Policy: The medical director shall obtain and maintain Iowa Controlled Substances Act (CSA) and federal Drug Enforcement Administration (DEA) registrations.

Procedure:

1. The service shall keep copies of the medical director's current CSA and DEA registrations.

2. At least 30 days prior to a change of address for the service program, the program shall submit an application to the Iowa Board of Pharmacy.

3. The Iowa Board of Pharmacy shall be notified in writing, by the service, prior to the change of medical director.

4. A new medical director shall obtain CSA and DEA registrations for the address of the primary program site, and submit copies to the service, prior to commencement of responsibilities as the medical director.

SECTION D: POLICIES AND PROCEDURES

Policy: The medical director and service director shall develop, implement and adhere to these written pharmacy procedures for the operation and management with respect to prescription drugs.

Procedure:

1. The service shall maintain documentation of periodic reviews of these policies and procedures by the medical director and service director.

2. The service shall maintain documentation of staff training to the service pharmacy agreement and policies & procedures when initiated and amended.

3. All records regarding prescription drugs shall be readily retrievable and available for inspection and copying by the Iowa Board of Pharmacy and the Bureau of Emergency and Trauma Services.

4. **Identification, Access and Administration**

   a. The service shall ensure that access is limited to appropriate staff and proper documentation is maintained.

   b. The service shall maintain a log of staff that has access to prescription drugs and to records regarding procurement, storage and administration of the drugs.

   c. The log shall be maintained in a readily-retrievable manner and be made available for inspection and copying by the Iowa Board of Pharmacy and the Bureau of Emergency and Trauma Services.

   d. The log shall include the staff member's printed name, unique identification used in program records, and level of certification used in the service records.

   e. Access to prescription drugs shall be limited to certified EMS providers that are listed on the pharmacy personnel log and System Registry roster.

   Type or legibly print a description of the security measures that limit access to individuals with the authority to administer prescription drugs. The procedure shall provide for the effective control against theft of, diversion of, or unauthorized access to prescription drugs, records for such drugs and patient records:

   f. EMS providers may administer prescription drugs that are within their Scope of Practice and authorized by the service medical director.

5. **Procurement, Storage, Inspection and Inventory Control**

   a. The medical director or service director may order and receive prescription drugs from an Iowa–licensed wholesaler or pharmacy.

   b. Records of ordering, receipt and administration of drugs shall be maintained by the service.

   c. The medical director and service director shall maintain, at the primary site, an accurate list of all prescription drugs.

d. The service shall maintain records of a monthly inspection of all drugs at the primary site and all satellites.

e. The inspection shall include removal of outdated or adulterated drugs that are quarantined for disposal.

f. Staff may handle drugs within their current scope of practice as defined by the Bureau of Emergency and Trauma Services.

g. All staff is authorized to perform and document inspections of security and temperature.

h. Storage at the primary site and all satellites will be in a designated, secure, clean and debris-free climate-controlled area.

i. Environmental temperatures shall be recorded on a monthly basis, at a minimum.

j. Drugs exposed to extreme temperatures (>104 degrees and <13 degrees Fahrenheit) shall not be administered to patients and removed from usable stock and quarantined for proper disposal.

k. The service director shall consult with the wholesaler or pharmacist regarding recalls and ensure removal, replacement and return or proper destruction of recalled drugs.

l. Expired, recalled and damaged drugs shall be removed from usable stock and quarantined for disposal or destroyed.

Type or print legibly to describe the process for proper disposal or destruction of quarantined (adulterated, damaged, outdated and recalled) drugs:

6. Replenishment

a. Service staff may request replenishment of drugs maintained at the service or satellites.

Type or print legibly to describe the replenishment process:

7. Protocols, Administration of Drugs Beyond the Limits of Protocols, Patient Care Reports

a. The medical director shall approve patient care protocols for all drugs carried by the service.

b. The service director shall ensure that the drugs and controlled substances carried by the service match the drug list in the approved patient care protocols.

c. Drugs may be administered beyond the limits of the patient care protocols provided that online or verbal medical direction has been obtained prior to administration.

d. Verbal orders for drugs not covered in the patient care protocols shall be repeated back to the physician or designee for verification.

e. Drugs administered outside the parameters of the approved patient care protocols shall be documented in the patient care report including the name of the authorizing prescriber and any person that may have relayed the order.

f. Patient care reports that include drugs administered outside the parameter of the approved patient care protocols are subject to an immediate written audit of the patient care report per the service Continuous Quality Improvement Policy.

8. Controlled Substances Administration, Destruction & Disposal, Inventories and Record Maintenance, Suspicion of Loss or Theft

a. Every inventory and other required records shall be maintained by the service and shall be readily retrievable and available for inspection and copying by the Iowa Board of Pharmacy and Bureau of Emergency and Trauma Services.

b. DEA Form 222 that is preprinted with the address of the primary site is required to be maintained at the primary site for the acquisition of each supply of a Schedule II controlled substance. The form shall be signed and dated as of the date the order is submitted for filing.

c. The medical director shall not pre-sign DEA Form 222 for subsequent completion.

d. A perpetual inventory (electronic or manual) of Schedule II controlled substances shall be maintained at the service.

i. An electronic inventory shall provide for a hard-copy print out for any specified period of time and shall include the current inventory quantities for each drug at the time the record is printed.

ii. Electronic entries may not be changed once recorded. Adjustments or corrections shall require a separate entry that includes the identity of the person making the correction and the reason for the correction.

iii. The perpetual inventory shall identify all receipts and disbursements of Schedule II controlled substances by name and National Drug Code.

iv. The perpetual inventory shall include patient administration, wastage, return to the pharmacy and disposal.

v. The record of receipt shall identify the source of the drug, the strength and dosage form, the quantity, the date, and name or the unique identification of the individual verifying receipt of the drug.

vi. The record of disbursement shall identify the date, the strength and dosage form, the quantity, and where and to whom the drug is disbursed or administered.

vii. The service director shall be responsible for reconciling the physical inventory of all Schedule II controlled substances with the perpetual inventory balance at least monthly.

viii. Any discrepancy shall be reported to the medical director.

e. The medical director shall document an annual accurate inventory of all controlled substances at the primary site and any satellites.

f. All controlled substance records for the service and any satellites shall be maintained at the primary site. The records will clearly identify which records are for the primary site and each of the satellite(s).

g. The service shall maintain records of destruction or disposal of controlled substances.

i. Outdated, adulterated or unwanted supply shall be quarantined until the controlled substance can be distributed for disposal. EMS personnel shall not destroy controlled substances, except during wastage.

ii. For destruction and disposal of controlled substances, the medical director shall use the services of a DEA-registered and Iowa-licensed disposal firm or other means approved by the board.

Type or print legibly to describe the method used to dispose of controlled substances:

iii. EMS personnel, the medical director or pharmacist may destroy or dispose of the unused portion of a controlled substance resulting from administration to a patient.

1. Wastage shall be conducted in the presence an EMS provider authorized to administer the drug, professional or technical pharmacy staff or a licensed healthcare professional.

2. Written or electronic records of controlled substance wastage shall be maintained by the service.

3. The records shall include legibly printed names and the signatures or other unique identification of the witness and of the individual wasting the controlled substance and:

a. The controlled substance wasted;
b. The date of destruction or disposition;
c. The quantity or estimated quantity of the wasted controlled substance;
d. Patient identification;

h. Upon suspicion of loss or theft of any controlled substance, the service shall notify, in writing, the medical director and the Bureau of Emergency and Trauma Services within 48 hours of the discovery of the theft or loss.

i. The medical director shall immediately notify, in writing, the Iowa Board of Pharmacy of any theft or significant loss of any controlled substance.

i. The DEA should be notified within one business day of any theft or significant loss of any controlled substance.

ii. A DEA Form 106 documenting the theft or loss shall be submitted to the Iowa Board of Pharmacy and DEA within 45 days of the determination of the theft or loss.

iii. Within seven days following the report of theft or significant loss, a registrant will develop and initiate implementation of an action plan to address the conditions that contributed to the theft or significant loss.

j. The incident report shall be maintained at the service.