ARC 3101C

PHARMACY BOARD[657]

Adopted and Filed

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby amends Chapter 11, "Drugs in Emergency Medical Service Programs," Iowa Administrative Code.

The amendments are the result of a general review of administrative rules pursuant to Iowa Code section 17A.7(2). These amendments update language to be consistent with current Iowa Code provisions and reorganize the chapter to provide clarity. These amendments require any entity, regardless of location, whose controlled substances are stored or handled at any primary program site of an emergency medical service program that services Iowa residents to obtain and maintain an Iowa Controlled Substances Act registration at the primary program site location.

Notice of Intended Action was published in the Iowa Administrative Bulletin as **ARC 2904C** on January 18, 2017.

The Board received two comments regarding this rule making. The comments did not express opposition to the rule making, but rather sought clarification to the identified rules. As a result, a minor addition was made to rule 657—11.8(124,147A,155A) relating to the employee identification log to clarify that the log must be maintained at the primary program site.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

The Board adopted these amendments on May 10, 2017.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code chapter 147A and sections 124.301, 155A.13, and 17A.7(2).

These amendments will become effective July 12, 2017.

The following amendments are adopted.

ITEM 1. Amend rule 657—11.1(124,147A,155A) as follows:

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

"Adulterated" means any drug or device that consists in whole or in part of any filthy, putrid, or decomposed substance.

"Ambulance service" means any privately or publicly owned service program that utilizes ambulances, including air transport vehicles, in order to provide patient transportation and emergency medical services.

"Authorized prescriber" means any provider who has prescriptive authority in the state of Iowa.

"Board" means the board of pharmacy.

"Bureau" means the Iowa department of public health, bureau of emergency ~~medical~~ and trauma services ~~(EMS)~~ (BETS).

"Controlled substance" means any drug that is identified in Schedules I through V of Iowa Code chapter 124, the Iowa uniform controlled substances Act.

"CSA registration" means a registration issued by the board pursuant to Iowa Code chapter 124, the Iowa uniform controlled substances Act.

"DEA" means the U.S. Department of Justice, Drug Enforcement Administration.

"DEA registration" means a registration issued by the DEA pursuant to 21 CFR Part 1301.

"Department" means the Iowa department of public health.

"Drug" means a substance as defined in Iowa Code section 155A.3(13) but does not include nonmedicated intravenous solutions such as saline.

"Emergency medical care provider" means an emergency medical care provider as defined in 641—131.1(147A).

"Emergency medical services" or *"EMS"* means an integrated medical care delivery system to provide emergency and nonemergency medical care ~~at the scene or during out-of-hospital patient transportation in an ambulance~~.

"Emergency medical technician" or *"EMT"* means any emergency medical technician or EMT as defined in 641—131.1(147A).

"Medical direction" means direction, advice, or orders provided, in accordance with written parameters and protocols, to emergency medical care personnel by a medical director, supervising physician, or physician designee.

"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.

"Medical director-based" means that ownership of the drugs maintained in and used by the service program remains with the medical director.

"Patient care report" ~~or *"PCR"*~~ means a computerized or written report that documents the assessment and management of the patient by the emergency medical care provider ~~in the out-of-hospital setting~~.

"Pharmacy-based" means that ownership of the drugs maintained in and used by the service program remains with the pharmacy.

"Physician" means any individual licensed under Iowa Code chapter 148, 150, or 150A.

"Physician assistant" or *"PA"* 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 care provided by emergency medical care providers.~~

"Primary program site" means the physical location from which the service program is operated and at which stock supplies of prescription drugs may be maintained and distributed to a program vehicle and a program substation.

"Program substation" means the physical location from which a service program is operated as a branch or extension of a primary program site, at which an emergency kit or supply of prescription drugs is maintained, and at which a stock supply of prescription drugs is not maintained.

"Protocols" means written direction and orders, consistent with the department's standard of care, that are to be followed by an emergency medical care provider in emergency and nonemergency situations. Protocols shall be approved by the service program's medical director and shall address the care of both adult and pediatric patients.

"Responsible individual" ~~or *"RI,"* as this term relates to prescription drugs in a medical director-based service, means the medical director for the service. In a pharmacy-based service, "responsible individual" means the pharmacist in charge of the pharmacy~~ means the individual who maintains legal responsibility of the prescription drugs and devices. "Responsible individual" includes the medical director in a medical director-based service program or the pharmacist in charge in a pharmacy-based service program.

"Service" or *"service program"* means any medical care ambulance service or nontransport service that has received authorization from the department.

"Service director" means the individual who is responsible for the operation and administration of a service program.

"Supervising physician" means any physician licensed under Iowa Code chapter 148, 150, or 150A who supervises and is responsible for medical direction of emergency medical care personnel when such personnel are providing emergency medical care.

ITEM 2. Amend rule 657—11.2(124,147A,155A) as follows:

657—11.2(124,147A,155A) Responsibility. ~~Pursuant to rules of the bureau, each~~ Each service program shall appoint a service director at the primary program site and shall have a responsible individual who

is responsible for ensuring that the management of all prescription drugs complies with federal and state laws and regulations. In service programs that maintain both a pharmacy-based service program agreement and a medical director-based service program agreement, the responsible individual for each service program agreement shall be responsible for ensuring the management of drugs under that individual's ownership. If more than one pharmacy enters into an agreement with a pharmacy-based service program, the pharmacist in charge at each pharmacy is responsible for the rules and laws pertaining to the specific prescription drugs, including controlled substances, that each pharmacy provides to the service program.

~~**11.2(1)** *Pharmacy-based.* In a pharmacy-based service program, the pharmacist in charge shall be responsible for ensuring that the management of all prescription drugs complies with federal and state laws and regulations. The pharmacist in charge shall not serve as the service director.~~

~~**11.2(2)** *Medical director-based.* In a medical director-based service program, the medical director shall be responsible for ensuring that the management of all prescription drugs complies with federal and state laws and regulations.~~

~~**11.2(3)** *Combination pharmacy-based and medical director-based.* If both pharmacy-based and medical director-based programs are in effect, the pharmacist in charge of the pharmacy and the medical director shall be responsible for management of the drugs owned by the pharmacy and by the medical director, respectively.~~

ITEM 3. Renumber rules **657—11.3(124,147A,155A)** and **657—11.4(124,147A,155A)** as **657—11.4(124,147A,155A)** and **657—11.5(124,147A,155A)**.

ITEM 4. Adopt the following **new** rule 657—11.3(124,147A,155A):

657—11.3(124,147A,155A) Registration required. In 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.

11.3(1) *Medical director-based service program.* In a medical director-based service program, CSA and DEA registrations shall be obtained for each primary program site. CSA and DEA registrations shall be obtained prior to procurement of any controlled substances for use in the service program. Separate registrations for program substations shall not be required. In a medical director-based service program, the CSA and DEA registrations shall be issued 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.

11.3(2) *Pharmacy-based service program.* In a pharmacy-based service program, the 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.

11.3(3) *Combination pharmacy-based and medical director-based service program.* 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 as provided by this rule. A medical director-based program shall also maintain a federal DEA registration as provided by this rule.

11.3(4) *Change of address of registered primary program site.* A registrant may apply to change the address of the registered primary program site by submitting a written request as provided in 657—subrule 10.11(2). The board and the DEA shall be notified in writing prior to a change of address of a registered primary program site.

11.3(5) *Discontinuation of medical director in a medical director-based service program.* If a medical director intends to terminate a written agreement with a service program pursuant to rule 657—11.5(124,147A,155A), the medical director shall provide written notification to the board at 400

S.W. Eighth Street, Suite E, Des Moines, Iowa 50309, pursuant to 657—subrule 10.11(6), to cancel the registration, including the effective date of the termination of the agreement. The registration certificate shall be returned to the board no later than ten days following the effective date of the termination of the agreement.

ITEM 5. Amend renumbered rule 657—11.4(124,147A,155A) as follows:

657—11.4(124,147A,155A) Written agreement. A signed, written ~~formal~~ agreement for the service program shall be maintained at the primary program site and be available for inspection and copying by the board, ~~or~~ its representative, or any other authorized individual.

11.4(1) *Pharmacy-based service programs.* An Iowa-licensed pharmacy may enter into an agreement with a service program located in the state. The agreement with the service program shall establish that the service program is operating as an extension of the pharmacy with respect to the prescription drugs the pharmacy provides to the service program. The agreement shall be signed by the pharmacist in charge and the service director at the primary program site. A copy of this agreement shall be maintained at both the pharmacy and the primary program site while the agreement is in effect. Nothing in this rule prohibits more than one pharmacy from entering into an agreement with a service program provided that each pharmacy complies with all rules and regulations for a pharmacy-based service program, including maintenance of all required records specific to each pharmacy's drugs.

11.4(2) *Medical director-based service programs.* ~~A service program shall maintain a formal written agreement with a medical director that is signed by the medical director and the service director.~~ An Iowa-licensed physician may enter into an agreement with a service program located in the state. The agreement shall be signed by the medical director and the service director and be maintained at the primary program site while the agreement is in effect. ~~The medical director of the service program shall maintain a CSA registration and a DEA registration at the primary program site as required by rule 657—11.6(124,147A,155A).~~ The agreement shall include an attestation that the medical director agrees to abide by these rules.

ITEM 6. Amend renumbered rule 657—11.5(124,147A,155A) as follows:

657—11.5(124,147A,155A) Termination of ~~services~~ agreement. ~~EMS services~~ A written agreement may be terminated at the discretion of either the ~~EMS~~ service program or the party or parties responsible for providing drugs to the ~~EMS~~ service program. Written notification of such termination shall be provided to the other party at least 30 days prior to termination of ~~services~~ the agreement. ~~Transfer of ownership of controlled substances shall be in compliance with rule 657—10.11(124).~~

11.5(1) *Pharmacy-based service programs.* Immediately upon discontinuation of ~~services~~ a written agreement, all controlled substances shall be jointly inventoried by the pharmacist in charge of the pharmacy that owns the drugs and the service director or their respective designees. A record of this inventory shall be maintained at the pharmacy for two years from the date of the inventory and shall be available for inspection and copying by the board, its representative, or any other authorized individual. All drugs and devices that are the property of the pharmacy shall be immediately returned to the pharmacy.

11.5(2) *Medical director-based service programs.* Immediately upon discontinuation of ~~services~~ a written agreement, all controlled substances shall be jointly inventoried by the medical director and the service director or their respective designees. A record of this inventory shall be maintained by the medical director for two years from the date of the inventory and shall be available for inspection and copying by the board, ~~the board's~~ its representative, or ~~another~~ any other authorized individual. All drugs and devices that are the property of the medical director shall be immediately returned to the medical director.

11.5(3) *Transfer of ownership.* If drugs in a service program are to be maintained under the ownership of a new pharmacy or medical director, such transfer of ownership shall be in compliance with 657—Chapter 10, 657—Chapter 17, and federal laws and regulations. Pursuant to rule

657—10.34(124,155A), the transfer of Schedule II controlled substances shall require an executed DEA Form 222.

ITEM 7. Rescind and reserve rule **657—11.6(124,147A,155A)**.

ITEM 8. Amend rule 657—11.8(124,147A,155A) as follows:

657—11.8(124,147A,155A) Identification.

~~**11.8(1)**~~ A log of employees who have access to prescription drugs and to records regarding procurement, storage, and administration of prescription drugs at the service program shall be maintained for two years and be available for inspection and copying by the board, ~~or~~ its representative, or any other authorized individual. This log shall include ~~the employees'~~ each employee's printed ~~names~~ name and ~~signatures~~ signature, printed and signed initials or other unique identification used in service program records, and the ~~employees' levels~~ employee's level of certification. A service program may maintain an electronic record of employee identification, including the employee's name, signature, unique identification used in the service program records, and level of certification. Such log shall be maintained at the primary program site for at least two years from the date of the employee's last date of employment with the service program and shall be available for inspection and copying by the board, its representative, or any other authorized individual.

~~**11.8(2)** Policies and procedures shall be developed, implemented, and adhered to that identify at least the following:~~

~~*a.* Who has access to drugs.~~

~~*b.* Who has authority to administer drugs.~~

~~*c.* Who has authority to order, receive, and distribute prescription drugs and devices.~~

ITEM 9. Amend rule 657—11.10(124,147A,155A) as follows:

657—11.10(124,147A,155A) Ownership of prescription drugs. All prescription drugs obtained for use in a service program shall be owned either by a pharmacy or by the medical director of the service program.

11.10(1) *Pharmacy-based service programs.* If the drugs are owned by ~~the~~ a pharmacy or more than one pharmacy pursuant to these rules, the service program shall be considered a pharmacy-based service program and shall comply with these rules as they pertain to a pharmacy-based service program.

11.10(2) *Medical director-based service programs.* If the drugs are owned by the medical director, the service program shall be considered a medical director-based service program and shall comply with these rules as they pertain to a medical director-based service program.

11.10(3) *Combination pharmacy-based and medical director-based service programs.* If the service program has entered into both pharmacy-based and medical director-based service program agreements, both the pharmacy and the medical director shall retain separate ownership of the prescription drugs supplied and shall comply with these rules as applicable. The primary program site shall maintain a list that identifies which prescription drugs are owned and supplied by each responsible individual.

11.10(4) *Transfer of ownership.* Any transfer of ownership of prescription drugs and devices in a service program shall be in compliance with 657—Chapter 10, 657—Chapter 17, and federal laws and regulations.

ITEM 10. Amend rule 657—11.11(124,147A,155A) as follows:

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

11.11(1) ~~Each service program shall, jointly with the~~ The service director, the medical director, and the responsible individual~~,~~ 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 in accordance with these rules. These policies and procedures shall be available for inspection and copying by the board, ~~the board's~~ its representative, or ~~another~~ any other authorized individual. The policies and procedures shall be periodically reviewed by the responsible individual, the medical director, and the

service director and shall identify the frequency of the review. 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~~, 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(124,147A,155A).

~~*b.*~~ *c.* Protocols for administration of drugs pursuant to rule 657—11.14(124,147A,155A).

~~*c.*~~ *d.* Administration of drugs outside the parameters of written protocols pursuant to rule 657—11.15(124,147A,155A).

~~*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. 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.

~~*e.*~~ *f.* Process for the return of drugs pursuant to rule 657—11.22(124,147A,155A).

~~*f.*~~ *g.* Out-of-date and adulterated drugs pursuant to rule 657—11.23(124,147A,155A).

~~*g.*~~ *h.* Drug and device recalls pursuant to rule 657—11.24(124,147A,155A).

i. Monthly inspections pursuant to rule 657—11.20(124,147A,155A).

j. Record retention as described in rule 657—11.34(124,147A,155A) and other applicable rules of the board.

ITEM 11. Amend rule 657—11.13(124,147A,155A) as follows:

657—11.13(124,147A,155A) Storage. Prescription drugs at primary program sites and program substations shall be stored in designated secure areas that are clean and free of debris, where temperature ~~and humidity are~~ is appropriately controlled, and in a manner to protect identity and integrity.

11.13(1) *Temperature.* ~~All drugs~~ Each drug shall be stored ~~at~~ within the ~~proper~~ temperature range required in the manufacturer labeling. The service program shall utilize a method to provide continuous temperature control or monitoring, such as a temperature indicator, which at a minimum identifies when the drugs have been exposed to extreme temperatures. The service program shall regularly, but at least weekly, verify and document verification that the drugs have not been exposed to extreme temperatures. Drugs that are subjected to extreme temperatures shall not be administered to patients and shall be ~~immediately removed from usable stock~~ quarantined and returned to the responsible individual for disposition. Extreme temperatures shall be defined as excessive heat greater than 40 degrees Celsius (104 degrees Fahrenheit) and, if the product requires protection from freezing temperatures, excessive cold less than -10 degrees Celsius (13 degrees Fahrenheit). ~~Disposal~~ Disposition of unusable drugs shall be in compliance with rule 657—11.32(124,147A,155A).

11.13(2) *Security.* The security of prescription drugs, records for such drugs, and patient records is the responsibility of the responsible individual and shall provide for the effective control against theft of, diversion of, or unauthorized access to drugs and records. ~~Policies and procedures for the security of prescription drugs shall provide for the effective control against theft of, diversion of, or unauthorized access to prescription drugs, records for such drugs, and patient records. These policies and procedures shall indicate who has access to prescription drugs.~~ Policies shall identify procedures that will utilize or require the signature of two service employees for each disbursement to ensure accountability for controlled substances.

ITEM 12. Amend rule 657—11.14(124,147A,155A) as follows:

657—11.14(124,147A,155A) Protocols. Every service program shall utilize department protocols as the standard of care. The service program medical director may ~~make changes to the department protocols~~ authorize an alternative protocol provided the ~~changes~~ directives are within the EMS provider's scope of practice ~~and~~, are within acceptable medical practice, and have been filed with the department. Prescription drugs shall be administered pursuant only to a written protocol or oral order by an authorized prescriber. ~~Records~~ A copy of the current ~~protocols~~ protocol shall be provided to and maintained by the responsible individual, ~~and~~ the service director, the primary program site and each program substation and shall be available for inspection and copying by the board, its representative, or any other authorized individual.

ITEM 13. Amend rule 657—11.15(124,147A,155A) as follows:

657—11.15(124,147A,155A) Administration of drugs beyond the limits of ~~the~~ a written protocol. Drugs~~, excluding Schedule II controlled substances in a pharmacy-based service, as provided in rule 657—11.16(124,147A,155A),~~ may be administered beyond the limits of ~~the~~ a written ~~protocols~~ protocol provided that medical direction from an authorized prescriber has been obtained prior to administration. The authorization shall be recorded in the patient care report documenting the identity of the authorizing prescriber. If an agent of the authorized prescriber relayed the order, the identity of the prescriber's agent, including the agent's first and last names and title, shall also be recorded. The administration of a Schedule II controlled substance in a pharmacy-based service program shall be documented pursuant to rule 657—11.16(124,147A,155A).

ITEM 14. Amend rule 657—11.16(124,147A,155A) as follows:

657—11.16(124,147A,155A) Administration of Schedule II controlled substances—pharmacy-based service program. In a pharmacy-based service program, Schedule II controlled substances may be administered to patients under the care of a service program, including administration beyond the limits of a protocol when authorized pursuant to rule 657—11.15(124,147A,155A), provided that a signed order is delivered by the authorized prescriber to the pharmacy within seven days of the date administration was authorized. The signed order shall contain all of the prescription information required pursuant to Iowa Code section 155A.27. The patient care report may be accepted as the required signed order if the patient care report includes the required prescription information, including an original signature of the authorizing prescriber.

ITEM 15. Amend rule 657—11.20(124,147A,155A) as follows:

657—11.20(124,147A,155A) Prescription drugs in ~~EMS~~ service programs. Prescription drugs maintained by a service program shall be owned by an Iowa-licensed pharmacy or the service program's medical director.

11.20(1) *Pharmacy-based service programs.* The pharmacist in charge, the medical director, and the service director shall jointly develop, consistent with the service program's protocol, a list of drugs to be maintained for administration by the service program. The pharmacy shall maintain ~~an accurate~~ a current list of all prescription drugs including controlled substances that the pharmacy maintains at the primary program site and at any program substation.

a. Replenishment. The responsible individual, the service director, or designee may request that replenishment supplies of drugs be maintained at the primary program site provided that the pharmacy has been supplied with administration records justifying the order. Records of the administration of Schedule III, IV, and V controlled substances and noncontrolled prescription drugs provided to and maintained at the pharmacy shall include, at a minimum: the patient's name; the name, strength, dosage form, and quantity of the drug administered; and the date ~~administered~~ of administration. Records of the administration of Schedule II controlled substances provided to and maintained at the pharmacy shall consist of a written prescription including all of the prescription information required pursuant to Iowa Code section 155A.27 or ~~a copy of~~ the patient care ~~record~~ report if the patient care ~~record~~ report includes the required prescription information, including an original signature of the authorizing prescriber. ~~The~~ A pharmacist shall ~~approve~~ verify the accuracy of every drug ~~taken from the pharmacy's dispensing stock prior to the transfer of the drug~~ to be disbursed to the primary program site. Documentation of this verification shall be maintained within the pharmacy records.

b. Replenishment using automated medication distribution system (AMDS). A pharmacy utilizing ~~a decentralized~~ an automated medication distribution system (AMDS) ~~pursuant to 657—Chapter 9~~ may authorize replenishment of the service program's drug supplies from the AMDS provided that a pharmacist verifies the drugs stocked in the AMDS component before the drugs are removed from the pharmacy. Service program personnel authorized to remove drugs from the AMDS for restocking the service program's supplies shall be assigned a unique identification and access code for the purpose of accessing the AMDS. Access by authorized service program personnel shall be restricted to specific drug products authorized for use by the service program. A pharmacist shall, within 72 hours, ~~verify~~ review the access of and removal of drugs from the AMDS by service program personnel and shall maintain documentation of that ~~verification~~ review within the pharmacy records.

c. Inspections. The pharmacist in charge shall ensure the completion of a monthly inspection of all prescription drugs maintained by the pharmacy at the primary program site and any program substation. Inspection shall include the removal of outdated or adulterated drugs. All drugs removed from ~~administration~~ service program stock shall be returned to the pharmacy. Records of inspection shall be maintained for two years from the date of the inspection at the pharmacy. The pharmacist in charge may delegate the ~~conduct~~ completion of the monthly inspection to another pharmacist, a pharmacist-intern, a certified pharmacy technician, or ~~the service director~~ another designee of the pharmacist in charge.

11.20(2) *Medical director-based service programs.* The medical director and the service director shall jointly develop, consistent with the service program's protocol, a list of drugs to be maintained for administration by the service program. The medical director shall maintain ~~an accurate~~ a current list of all prescription drugs including controlled substances that the medical director maintains at the primary program site and at any program substation. ~~EMS personnel shall have authority to handle prescription drugs and devices pursuant to their scope of practice as defined by the bureau.~~

a. Replenishment. All drugs procured for administration in a medical director-based service program shall be obtained from an Iowa-licensed wholesaler, ~~a~~ pharmacy, or ~~an~~ authorized prescriber.

b. Inspections. The medical director shall ensure the completion of a monthly inspection of all prescription drugs maintained by the medical director at the primary program site and any program substation. Inspection shall include the removal of outdated or adulterated drugs. Records of inspection shall be maintained for two years from the date of the inspection at the primary program site or the program substation. The medical director ~~or service director~~ may ~~designate EMS personnel to conduct~~ delegate the completion of the required inspections to the service director or other designee.

ITEM 16. Amend rule 657—11.22(124,147A,155A) as follows:

657—11.22(124,147A,155A) Return of drugs. Drugs that have been removed from ~~administration~~ service program stock shall be returned to the responsible individual. In a pharmacy-based service program, drugs returned from the service program to the ~~base~~ pharmacy may be used by the pharmacy for subsequent dispensing or administration provided the drugs are not outdated or adulterated. Records

of the return of prescription drugs shall be maintained by the responsible individual for two years from the date of the return.

ITEM 17. Amend rule 657—11.23(124,147A,155A) as follows:

657—11.23(124,147A,155A) Out-of-date drugs or devices. Any drug or device bearing an expiration date shall not be administered beyond the expiration date of the drug or device. Outdated drugs or devices shall be removed from ~~administration~~ service program stock and quarantined until such drugs or devices are ~~properly disposed of or, if the service program is a pharmacy-based service,~~ returned to the ~~base pharmacy~~ responsible individual for disposition. ~~Outdated drugs are the property of the responsible individual and shall be disposed of appropriately. Outdated controlled substances shall be disposed of pursuant to rule 657—11.32(124,147A,155A).~~

ITEM 18. Amend rule 657—11.24(124,147A,155A) as follows:

657—11.24(124,147A,155A) Product recall. ~~All~~ Each service ~~programs~~ program shall have a ~~system~~ procedure for removal from ~~administration~~ service program stock all ~~prescription~~ drugs or devices subject to a product recall. The ~~system~~ procedure shall include action appropriate to the direction or requirements of the recall.

ITEM 19. Amend rule 657—11.26(124,147A,155A) as follows:

657—11.26(124,147A,155A) Controlled substances records.

11.26(1) *Records maintained.* Every inventory or other record required to be maintained under this chapter, 657—Chapter 10, or Iowa Code chapter 124 shall be maintained at the primary program site or the program substation and by the pharmacy if the service program is pharmacy-based. All required records shall be available for inspection and copying by the board, ~~or~~ its representative, or any other authorized individual for at least two years from the date of such record. Controlled substances records shall be maintained in a readily retrievable manner. Schedule II controlled substances records shall be maintained separately from all other records of the registrant.

11.26(2) *Receipt and disbursement records in medical director-based service programs.* Any pharmacy or other authorized registrant that provides controlled substances for a medical director-based service program shall provide to the service program a record of the disbursement and maintain ~~records~~ a record of ~~receipt and~~ the disbursement ~~that~~ pursuant to rule 657—10.34(124,155A). The service program shall retain the record on which an authorized individual shall sign and record the actual date of receipt. The record shall include the following:

a. to *e.* No change.

ITEM 20. Amend rule 657—11.27(124,147A,155A) as follows:

657—11.27(124,147A,155A) Ordering Schedule II controlled substances—medical director-based service programs. Except as otherwise provided by 657—subrule 10.34(7) and under federal law, a DEA Form 222, preprinted with the address of the primary program site, is required to be maintained at the primary program site for the acquisition of each supply of a Schedule II controlled substance. The order form shall be executed only by the medical director named on the order form or by an authorized signer designated pursuant to a properly executed power of attorney. A DEA Form 222 shall be dated and signed as of the date the order is submitted for filling. A medical director or authorized signer shall not pre-sign a DEA Form 222 for subsequent completion. All Schedule II order forms shall be maintained at the primary program site and shall be available for inspection and copying by the board, ~~or~~ its representative, or any other authorized individual for a period of two years from the date of the record.

ITEM 21. Amend rule 657—11.29(124,147A,155A) as follows:

657—11.29(124,147A,155A) Schedule II controlled substances perpetual inventory. Each service program located in Iowa that administers Schedule II controlled substances shall maintain a perpetual

inventory for all Schedule II controlled substances pursuant to the requirements of this rule. All records relating to the perpetual inventory shall be maintained at the primary program site and shall be available for inspection and copying by the board, ~~or~~ its representative, or any other authorized individual for a period of two years from the date of the record.

11.29(1) *Record.* The perpetual inventory record may be maintained in a ~~manual~~ hard-copy or ~~an~~ electronic record format. Any electronic record shall provide for hard-copy printout of all transactions recorded in the perpetual inventory record for any specified period of time and shall state the current inventory quantities of each drug at the time the record is printed. ~~An electronic~~ A record entry, once recorded, shall not be changed; any adjustments or corrections shall require entry of a separate record as provided in subrule 11.29(3).

11.29(2) *Information included.* The perpetual inventory record shall identify all receipts and disbursements of Schedule II controlled substances by drug name or by National Drug Code (NDC), including each patient administration, wastage, and return of a drug to the responsible individual~~, and disposal of a drug~~. The record of receipt shall also identify the source of the drug, the strength and dosage form, the quantity, the date of receipt, and the name or unique identification of the individual verifying receipt of the drug. The disbursement record shall identify where or to whom the drug is disbursed or administered, the strength and dosage form, the quantity, the date of disbursement or administration, and the name or unique identification of the individual responsible for the disbursement. Receipts and disbursements shall be recorded in the perpetual inventory as soon as practicable but no later than 24 hours after the receipt, disbursement, or administration.

11.29(3) *Adjustments or corrections to the record.* Any adjustments or corrections made to the perpetual inventory shall include the identity of the person making the adjustment or correction and the reason for the adjustment or correction.

11.29(4) *Reconciliation.* The pharmacist in charge or designee in a pharmacy-based service program, or the medical director or designee in a medical director-based service program, shall be responsible for reconciling the ~~physical~~ perpetual inventory record of all Schedule II controlled substances with the ~~perpetual~~ physical inventory ~~balance on a periodic basis but no less frequently than~~ at least monthly. Any discrepancy shall be reported within 24 hours of the discovery to the ~~medical director and to the pharmacist in charge if the service program is a pharmacy-based program~~ responsible individual for investigation.

ITEM 22. Amend rule 657—11.30(124,147A,155A) as follows:

657—11.30(124,147A,155A) Controlled substances annual inventory. An accurate inventory shall be taken annually of all controlled substances maintained at the primary program site and program substations. Controlled substances in a pharmacy-based service program shall be included in the pharmacy's annual controlled substances inventory. The inventory record shall identify the drug name or National Drug Code (NDC) and the exact quantity under the control of the service program including drugs in replenishment stock and quarantined stock. The inventory record shall contain the date and time the inventory was taken and the printed name and signature of the individual or individuals responsible for the inventory record. Records of the inventory shall be maintained pursuant to rule 657—11.34(124,147A,155A).

ITEM 23. Amend rule 657—11.32(124,147A,155A) as follows:

657—11.32(124,147A,155A) ~~Destruction or disposal~~ Disposition of controlled substances. ~~Disposal or destruction~~ Disposition of controlled substances shall be pursuant to the requirements of this rule, ~~and~~ rule 657—11.29(124,147A,155A), 657—Chapter 10, and federal regulations. Records shall be maintained at the primary program site and, if the service program is ~~a~~ pharmacy-based ~~service~~, records shall be maintained at the pharmacy.

11.32(1) *Outdated, adulterated, or unwanted supply.* ~~EMS personnel shall not destroy any controlled~~ Controlled substances shall not be destroyed except as provided in subrule 11.32(2). Any drug that requires ~~disposal or destruction~~ disposition shall be ~~removed from administration stock and~~

quarantined until the drug can be returned to the responsible individual. The responsible individual shall ~~dispose of or destroy~~ ensure the proper disposition of controlled substances according to the following procedures:

a. and *b.* No change.

11.32(2) *Administration wastage.* Except as otherwise specifically provided by federal or state law or rules of the board, the unused portion of a controlled substance resulting from administration to a patient may be destroyed or otherwise disposed of by the administering ~~EMS~~ service program personnel, the medical director, or a pharmacist. Any wastage of a controlled substance shall be conducted in the presence of a responsible adult witness who is ~~a member of the EMS team~~ an authorized service program employee, a member of the professional or technician pharmacy staff, or a licensed health care professional. A written or electronic record of controlled substance wastage shall be ~~made~~ created and maintained at the primary program site and, if the service program is ~~a~~ pharmacy-based ~~service~~, at the pharmacy, for a minimum of two years following the ~~destruction or other disposal~~ disposition. The record shall include the signatures or other unique identification of the witness and of the individual destroying or otherwise disposing of the wastage of the controlled substance and shall identify the following:

a. to *d.* No change.

e. ~~The~~ If either individual involved in the wastage is not identified in the service program identification log, the legibly printed first and last names and title of the ~~person wasting the unused portions of the controlled substance and of the qualified witness~~ individual.

ITEM 24. Amend rule 657—11.33(124,147A,155A) as follows:

657—11.33(124,147A,155A) Report of loss or theft of controlled substance. Upon suspicion of any loss or theft of a controlled substance, the service director shall immediately notify the responsible individual. The responsible individual shall ~~notify the DEA pursuant to rule 657—10.16(124) and federal regulations~~ provide notice and reporting as required in rule 657—10.16(124). ~~The responsible individual shall report in writing, on forms provided by the board or as directed by the board, any theft or significant loss of any controlled substance. The report shall be submitted to the board office within two weeks of the discovery of the theft or loss. A copy of the report shall be maintained at the primary program site and, if the program is a pharmacy-based service, at the pharmacy.~~

ITEM 25. Amend rule 657—11.34(124,147A,155A) as follows:

657—11.34(124,147A,155A) Records. If a service program includes a primary program site and one or more program substations, ~~the records of the service program~~ each record shall identify the ~~primary program site and each program substation~~ specific location to which it applies. Records regarding service program substation activities, including drug supply and administration records, may be maintained at the primary program site but shall clearly identify the program substation to which the records apply. All records regarding prescription drugs and devices in a service program shall be maintained for two years from the date of the activity or record and be available for inspection and copying by the board, ~~or~~ its representative, or any other authorized individual.

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