CHAPTER 15
CORRECTIONAL PHARMACY PRACTICE

657—15.1(155A) Purpose and scope. It is the intent of these rules to authorize the department of corrections to distribute prescription drugs to patients in correctional facilities from one or more correctional pharmacies. Each correctional pharmacy shall be responsible for the provision of pharmacy services for a specific number of correctional facilities. The correctional pharmacies may be located on the grounds of a correctional facility or may be located off site from all facilities. The correctional pharmacies shall be licensed by the board with limited-use pharmacy licenses designated as correctional pharmacy licenses. Pharmacists shall be responsible for any delegated act performed by supportive personnel under the pharmacists' supervision. The requirements of these rules for correctional pharmacy practice are in addition to the requirements of 657—Chapter 8 and other rules of the board relating to the services provided by the pharmacies.
[**ARC 8670B**, IAB 4/7/10, effective 5/12/10]

657—15.2(126,155A) Definitions. For purposes of this chapter, the following definitions shall apply:

"Board" means the Iowa board of pharmacy.

"Department" means the Iowa department of corrections.

"Emergency/first dose drug supply" means a limited inventory of drugs stored outside the correctional pharmacy and accessible to designated health care staff for the purpose of initiating emergency or first dose prescription drug orders issued during periods when the pharmacist is unavailable.

"Medication administration record" means the record of the administration of drugs to patients.

"Med-pak" means a customized patient medication package prepared for a specific patient which comprises a series of immediate containers containing prescribed solid oral dosage forms, each container being labeled with the time or the appropriate period for the patient to take its contents.

"Prescription drug order" means an order that is for a drug or device for a patient in custody status in a correctional facility, that is originated by a practitioner authorized to prescribe, and that meets the information requirements for a prescription drug order but is recorded, distributed, and administered as though it were a medication order.

"Qualified individual" means a pharmacist, a person who has successfully completed a medication administration course, or a person specifically authorized under pertinent sections of the Iowa Code to administer prescription drugs.

"Single unit package" means a package that contains one discrete pharmaceutical dosage form.

"Unit dose dispensing system" means a drug distribution system utilizing single unit, unit dose, or unit of issue packaging in a manner that helps reduce or remove traditional drug stocks from resident care areas and enables the selection and distribution of drugs to be pharmacy-based and controlled.

"Unit dose package" means a package that contains that particular dose of a drug ordered for the patient for one administration time. A unit dose package is not always a single unit package.

"Unit of issue package" means a package that provides multiple units or doses attached to each other but separated in a card or specifically designed container.
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657—15.3(155A) Pharmacist in charge. One professionally competent, legally qualified pharmacist who is licensed to practice pharmacy in Iowa shall be the pharmacist in charge of the correctional pharmacy and shall be responsible for, at a minimum, the following:

1. Ensuring that the pharmacy utilizes an ongoing, systematic program for achieving performance improvement and ensuring the quality of pharmaceutical services;
2. Ensuring that the pharmacy employs an adequate number of qualified personnel commensurate with the size and scope of services provided by the pharmacy;
3. Ensuring that a quarterly inspection of all pharmaceuticals located at the correctional facility, including any emergency/first dose drug supply located outside the confines of the pharmacy, is completed and documented;

4. Ensuring the availability of any equipment and references necessary for the particular practice of pharmacy;

5. Preparing written policies and procedures governing pharmacy functions; periodically reviewing and revising those policies and procedures to reflect changes in processes, organization, and other pharmacy functions; ensuring that policies and procedures are consistent with board rules; and ensuring that all pharmacy personnel are familiar with the policies and procedures;

6. Ensuring that a pharmacist performs prospective drug use reviews as specified in rule 657—8.21(155A);

7. Ensuring that a pharmacist provides drug information to other health professionals, to other caregivers, and to patients as required or requested;

8. Dispensing drugs to patients, including the packaging, preparation, compounding, and labeling functions performed by pharmacy personnel;

9. Delivering drugs to the patient or the patient's agent;

10. Ensuring that patient drug records are maintained as specified in rule 657—15.8(124,126,155A);

11. Training pharmacy technicians and pharmacy support persons;

12. Establishing policies and procedures for the procurement and storage of prescription drugs and devices and other products dispensed from the pharmacy;

13. Disposing of and distributing drugs from the pharmacy;

14. Maintaining records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs as required by applicable state and federal laws, rules, and regulations;

15. Establishing and maintaining effective controls against the theft or diversion of prescription drugs and records for such drugs;

16. Ensuring the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.

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657—15.4(155A) Reference library. References may be printed or computer-accessed. Each correctional pharmacy shall have on site, at a minimum, one current reference from each of the following categories, including access to current periodic updates.

1. The Iowa Pharmacy Law and Information Manual.

2. A patient information reference that includes or provides patient information in compliance with rule 657—6.14(155A).

3. A reference on drug interactions.

4. A general information reference.

5. A drug equivalency reference.

6. A reference on natural or herbal medicines.

7. The readily accessible telephone number of a poison control center that serves the area.

8. Additional references as may be necessary for the pharmacist to adequately meet the needs of the patients served.

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657—15.5(124,155A) Security. The pharmacy shall be located in an area or areas that provide for effective control against theft of, diversion of, and unauthorized access to prescription drugs and pharmacy records. The following conditions shall be met to ensure appropriate control over drugs and chemicals in the pharmacy:

15.5(1) *Locked areas.* All areas occupied by the correctional pharmacy or where drugs or devices are maintained or stored shall be lockable by a key, combination, or electronic device so as to prevent access by unauthorized personnel and shall be locked when unoccupied or unattended.

15.5(2) *Access when pharmacist absent.* The pharmacist in charge, with the concurrence of the department, shall establish and implement policies and procedures for the security of the correctional pharmacy. Policies and procedures shall identify who will have access to the pharmacy, what areas may

be accessed, and the procedures to be followed for obtaining drugs and chemicals when the pharmacist is absent from the pharmacy.

15.5(3) *Pharmacist responsibility.* Each pharmacist, while on duty, shall be responsible for the security of the correctional pharmacy. This responsibility includes provisions for effective control against theft of, diversion of, or unauthorized access to prescription drugs or devices, controlled substances, records for such drugs and devices, and patient records as provided in 657—Chapter 21 and rule 657—8.16(124,155A). Policies and procedures shall identify the days and hours the pharmacy shall be open. A pharmacist shall be on site during all times that the pharmacy is open.

15.5(4) *Drugs in the correctional facility.* All drugs distributed from the pharmacy to areas of the correctional facility for subsequent administration to patients shall be kept in locked storage when not in use. Policies and procedures shall identify the qualified individuals who are authorized to access these drugs and the process to be followed for their removal.

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657—15.6 Reserved.

657—15.7(124,126,155A) Training and utilization of pharmacy technicians or pharmacy support persons. All correctional pharmacies utilizing pharmacy technicians or pharmacy support persons shall develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy technicians and pharmacy support persons appropriate to the practice of pharmacy at that licensed location. Pharmacy policies shall specify the frequency of the review. Pharmacy technician and pharmacy support person training shall be documented and maintained by the pharmacy for the duration of employment. Policies and procedures and documentation of pharmacy technician and pharmacy support person training shall be available for inspection by the board or an agent of the board.

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657—15.8(124,126,155A) Drug distribution and dispensing controls. Prescription drugs shall be distributed or dispensed only from the original or a properly verified prescription drug order. There shall be no transcribing of prescription drug orders by nursing staff or clerical staff except for their own records.

15.8(1) *Required information.* Prescription drug orders written in patient health records shall include the following information:

a. Patient name, identification number, and correctional facility location;
b. Drug name, strength, dosage form, and quantity or duration;
c. Directions for use of the drug;
d. Date the prescription drug order is authorized;
e. Prescriber's name, signature, and office address;
f. Prescriber's DEA number for controlled substances.

15.8(2) *Original maintained.* The original prescription drug order and the medication administration record shall be maintained for a minimum of two years in the patient's health record.

15.8(3) *Effect upon transfer of patient.* Current prescription drug orders remain in effect when a patient is transferred to another correctional facility.

15.8(4) *Unit dose dispensing.* Drugs dispensed in a unit dose dispensing system for subsequent administration by nurses or other qualified individuals shall be packaged and labeled by pharmacy staff in compliance with the provisions of rule 657—22.1(155A). Policies and procedures shall be implemented that include, but are not limited to, the following:

a. Return and reuse of drugs;
b. Expiration dating;
c. Record keeping.

15.8(5) *Med-pak dispensing.* Drugs may be dispensed in med-pak dispensing systems for subsequent administration by nurses or other qualified individuals. Policies and procedures shall be

implemented that are in accordance with rule 657—22.5(155A) and include, but are not limited to, the following:

a. Return and reuse of containers;

b. Expiration dating;

c. Record keeping.

15.8(6) *Drug administration.* Only a licensed health care professional authorized to administer drugs or a qualified individual shall administer to a patient prepackaged drugs from the supply distributed by the pharmacy. Documentation of administration shall be recorded in the medication administration record. The single unit, unit dose, or med-pak packaging shall remain intact to the point of administration.

15.8(7) *Dispensing for patient self-administration.* Drugs dispensed for self-administration by a patient shall be packaged and labeled in accordance with rule 657—6.10(126,155A).

15.8(8) *Labeling of drugs under special circumstances.*

a. Insulin, ophthalmics, otic preparations, inhalers, nasal sprays, topicals, and other similarly packaged drugs. A label shall be affixed to the immediate container showing at least the patient's name and ID number. A label that complies with 657—subrule 6.10(1) shall be affixed to the outer container.

b. Leave and release drugs. Labeling of prescription drugs for patients leaving the correctional facility for temporary absences in excess of 24 hours, such as court appearances, and for patients being released from custody shall comply with 657—subrule 6.10(1) before the drug is removed from the facility. The dispensing pharmacy shall be responsible for packaging and labeling leave and release drugs in compliance with this paragraph.

15.8(9) *Drug product selection.* Correctional pharmacies shall be exempt from the patient notification requirements of Iowa Code section 155A.32 when exercising drug product selection.

15.8(10) *Emergency/first dose drug supply.* An emergency/first dose drug supply of prescription drugs may be supplied to a correctional facility for use by authorized personnel pursuant to rule 657—22.7(124,155A). Only pharmacists, pharmacist-interns, and pharmacy technicians may restock, replace, or return drugs to the emergency/first dose drug supply. A drug shall be removed from the emergency/first dose drug supply only pursuant to a valid prescription drug order. The pharmacy shall be notified of the removal and administration of a drug from the emergency/first dose drug supply. The pharmacist shall perform drug use review prior to the administration of a second dose. All drugs removed from the emergency/first dose drug supply that are not administered, including any wastage, shall be returned to the pharmacy. A written or electronic record shall be made of all removals from the emergency/first dose drug supply. The record shall include the following information:

a. Patient's name and identification number;

b. Prescriber;

c. Name, strength, dosage form, and quantity of the drug removed;

d. Signature, unique identification, or initials of the authorized person removing the drug;

e. Date and time the drug was removed;

f. Returns of unused drugs to the pharmacy.

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657—15.9 Reserved.

657—15.10(124,126,155A) Policies and procedures. The pharmacist in charge shall develop and implement written policies and procedures for the pharmacy drug distribution system consistent with board rules and department policies and procedures pertaining to pharmaceutical services. Pharmacy policies and procedures shall address, but not be limited to, the following:

1. Controlled substances;
2. Formulary or drug list;
3. Stop orders;
4. Drug sample use and distribution;
5. Drug recalls;
6. Outdated drugs;

7. Patient records;
8. Inspection of drug inventories;
9. Adverse reaction reports;
10. Leave and release drugs;
11. Emergency/first dose drug supply;
12. Drugs brought into the facility;
13. Medication administration and records;
14. Drug compounding;
15. Sterile products;
16. Access to the pharmacy in the absence of the pharmacist;
17. Transfers of drugs between facilities and correctional pharmacies;
18. Transfers of prescription drug orders between correctional pharmacies;
19. Delivery of drugs;
20. Notification when a drug or device is not available;
21. Drug destruction within the pharmacy;
22. Return of unused drugs.

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These rules are intended to implement Iowa Code sections 124.301, 124.303, 124.306, 124.308, 126.10, 126.11, 155A.6A, 155A.13, 155A.27, 155A.28, 155A.31, 155A.32, and 155A.34 through 155A.36 and 2009 Iowa Code Supplement section 155A.6B.

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