

CHAPTER 23
CARE FACILITY PHARMACY PRACTICE

657—23.1(155A) Purpose and scope. The purpose of this chapter is to identify the minimum standards for licensed pharmacies in this state providing pharmacy services to care facilities.
[ARC 3859C, IAB 6/20/18, effective 7/25/18]

657—23.2(155A) Definitions. For the purposes of this chapter, the following definitions shall apply:

“Authorized collection program” means a program administered by a registrant that has modified its registration with DEA to collect controlled substances for the purpose of disposal. Federal regulations for such programs can be found at www.deadiversion.usdoj.gov/drug_disposal.

“Care facility” or *“facility”* means:

1. A facility licensed by the Iowa department of inspections and appeals under Iowa Code chapter 135C or 135H;
2. A hospital-based long-term care unit certified under 42 CFR, Part 483, Subpart B;
3. An inpatient hospice certified under 42 CFR, Part 418;
4. A group living facility wherein health care-related services are provided by the facility; or
5. A health care facility registered with the board under Iowa Code chapter 124.

“Care facility pharmacy” or *“provider pharmacy”* means a pharmacy that provides pharmacy services to a care facility.

“Consultant pharmacist” in a care facility means an Iowa-licensed pharmacist who is responsible for developing, coordinating, and supervising pharmaceutical services in a care facility on a regularly scheduled basis.

“DEA” means the United States Department of Justice, Drug Enforcement Administration.

“Medication order,” as used in these rules, means an order from a practitioner or the practitioner’s authorized agent for administration of a drug or device. For purposes of this chapter, “medication order” includes a prescription.

“Provider pharmacist” means a pharmacist licensed to engage in the practice of pharmacy who is employed by or contracted to a care facility pharmacy or a provider pharmacy and who is responsible for supervising the accurate dispensing and proper delivery of drugs and devices to a care facility located within this state. These services shall include, at a minimum, proper medication labeling, storage, transport, record keeping, and prospective drug utilization review in compliance with all federal and state laws and regulations.

“Unit dose dispensing system” means a drug distribution system utilizing unit dose packaging.
[ARC 3859C, IAB 6/20/18, effective 7/25/18]

657—23.3(124,155A) Freedom of choice. Pursuant to 657—subrule 8.11(2), no pharmacist or pharmacy shall participate in any agreement or plan that infringes on any resident’s right to freedom of choice as described in rules of the department of inspections and appeals.

[ARC 3859C, IAB 6/20/18, effective 7/25/18]

657—23.4(124,155A) Responsibilities. The pharmacist in charge and staff pharmacists in any pharmacy providing pharmaceutical services to care facility patients shall share responsibility for:

1. Dispensing drugs pursuant to a medication order for an individual resident that are properly labeled and packaged in a manner consistent with the facility’s established drug delivery system and in compliance with applicable board rules for the drug delivery system.
2. Affixing labels to each container of drugs for residents in care facilities, in compliance with 657—Chapter 22 or rule 657—6.10(126,155A), 657—23.13(124,155A), or 657—23.14(124,155A).
3. Maintaining records as required by law and maintaining accurate control over and accountability for all drugs and prescription devices.
4. Complying with a drug recall procedure, established pursuant to rule 657—8.3(155A), that protects the health and safety of residents.
5. Providing 24-hour emergency service either directly or by contract with another pharmacy.

6. Conducting prospective drug use review pursuant to rule 657—8.21(155A) and subrule 23.5(1).
7. Providing sufficient and accurate information to facility staff regarding the appropriate administration and use of all dispensed drugs and devices.
8. Communicating with the consultant pharmacist and the facility staff regarding concerns and resolution thereof.

[ARC 1961C, IAB 4/15/15, effective 5/20/15; ARC 3859C, IAB 6/20/18, effective 7/25/18]

657—23.5(124,155A) Emergency drugs. A supply of emergency drugs may be provided by one or more pharmacies to the facility pursuant to rule 657—22.7(124,155A).

23.5(1) Emergency medication order—pharmacist review. When an emergency drug is provided pursuant to rule 657—22.7(124,155A), the medication order shall be reviewed by the resident's dispensing pharmacist prior to the administration of a second dose.

23.5(2) Other emergency drugs and devices. In addition to emergency drug supplies, a care facility may maintain a stock of intravenous fluids, irrigation fluids, heparin flush kits, medicinal gases, sterile water and saline, and prescription devices. Such stock shall be limited to a listing to be determined by the provider pharmacist in consultation with the consultant pharmacist and the medical director and director of nursing of the facility.

[ARC 0749C, IAB 5/29/13, effective 7/3/13; ARC 3859C, IAB 6/20/18, effective 7/25/18]

657—23.6(124,155A) Space, equipment, and supplies. Rescinded ARC 3859C, IAB 6/20/18, effective 7/25/18.

657—23.7(124,155A) Policies and procedures. Pursuant to rule 657—8.3(155A), each pharmacy shall have policies and procedures related to all aspects of the pharmacy's packaging and dispensing responsibilities to the residents of a care facility. The policies and procedures shall be maintained at the provider pharmacy and shall be available to the facility and the consultant pharmacist. Policies and procedures shall include, at a minimum:

1. Methods used to dispense and deliver drugs and devices to the facility in a timely fashion.
2. Proper notification to the facility when a drug or device is not readily available.
3. Proper labeling requirements to meet the needs of the facility and which are consistent with state and federal laws and regulations.
4. Appropriate drug destruction or return of unused drugs, or both, consistent with state and federal laws and regulations.
5. An automatic stop order policy to ensure that drug orders are not continued inappropriately.
6. Methods to ensure that all discontinued, outdated, deteriorated, or improperly labeled drugs and all containers with worn, illegible or missing labels are disposed of so as to render them unusable and protected from unauthorized possession or use.

[ARC 1961C, IAB 4/15/15, effective 5/20/15; ARC 3859C, IAB 6/20/18, effective 7/25/18]

657—23.8 Reserved.

657—23.9(124,155A) Medication orders. Drugs and prescription devices may be dispensed only upon orders of an authorized prescriber or authorized pharmacist as part of a collaborative drug therapy management protocol pursuant to rule 657—39.13(155A).

23.9(1) Requirements for noncontrolled substances. New medication orders transmitted to the pharmacy for noncontrolled substances shall, at a minimum, contain resident name, drug name and strength, directions for use, date of order, and name of prescriber.

23.9(2) Requirements for controlled substances. New medication orders transmitted to the pharmacy for controlled substances, including Schedule II controlled substances, shall be in compliance with 657—Chapter 10, 657—Chapter 21, and federal regulations.

23.9(3) Who may transmit medication orders. An authorized prescriber or prescriber's agent may transmit to the pharmacy a medication order lawfully ordered by an authorized prescriber. An order transmitted by the prescriber's agent shall include the agent's first and last names and title. Specifically

for the transmission of a controlled substance prescription, a member of the care facility staff is an agent of the prescriber only if the prescriber maintains an office in the facility or there exists an agent agreement between the prescriber and the care facility staff member.

[ARC 9912B, IAB 12/14/11, effective 1/18/12; ARC 2197C, IAB 10/14/15, effective 11/18/15; ARC 3859C, IAB 6/20/18, effective 7/25/18]

657—23.10(124,155A) Stop orders. Rescinded ARC 3859C, IAB 6/20/18, effective 7/25/18.

657—23.11(124,155A) Drugs dispensed—general requirements.

23.11(1) Labeling. All prescription containers, other than those dispensed pursuant to 657—Chapter 22, rule 657—23.13(124,155A), or rule 657—23.14(124,155A), shall be properly labeled in accordance with 657—subrule 6.10(1).

a. If a label change is required to reflect a change in directions, the pharmacist shall be responsible for affixing the correct label to the container. Care facility personnel shall not be directed by the pharmacy to affix such a label to the drug container.

b. Direction change labels that notify care facility personnel that a change in directions for the drug has taken place may be used and affixed to the container by facility personnel so as not to deface the original label.

23.11(2) Medication order required. Dispensing of all drugs to the facility shall be pursuant to a medication order for an individual resident except as provided in rules 657—23.5(124,155A) and 657—23.14(124,155A).

23.11(3) Prescription containers. All prescription containers utilized for dispensing drugs to a care facility shall meet minimum requirements as established by the United States Pharmacopoeia and 657—Chapter 22. When applicable, light-resistant packaging shall be used.

23.11(4) Floor stock. Prescription drugs, as defined by Iowa Code section 155A.3(38), shall not be floor-stocked in a care facility except as provided in this subrule or in subrule 23.5(2). Bulk supplies of nonprescription drugs may be maintained as provided in subrule 23.13(3). Any pharmacy that utilizes a floor stock distribution system pursuant to this subrule shall develop and implement procedures to accurately establish proof of use of prescription drugs and shall maintain a perpetual inventory, whether by electronic or manual means, of all prescription drugs so dispensed. A floor stock distribution system for prescription drugs may be permitted only under the following circumstances:

a. A licensed pharmacy under the direct supervision and control of a pharmacist is established in the facility; or

b. The facility and the hospital wherein the licensed pharmacy is located are both licensed under Iowa Code chapter 135B with a single hospital license.

[ARC 2408C, IAB 2/17/16, effective 3/23/16; ARC 3859C, IAB 6/20/18, effective 7/25/18]

657—23.12 Reserved.

657—23.13(124,155A) Labeling drugs under special circumstances.

23.13(1) Drug products of insufficient size to accommodate pharmacy labeling. Drug products, such as insulin, ophthalmics, otic preparations, and injectables, that are of insufficient size to accommodate a full pharmacy label shall be dispensed with a label affixed to the immediate container showing at least the resident's name and location.

23.13(2) Legend solutions—irrigation and infusion. Legend irrigation solutions and infusion solutions supplied by a pharmacy may be stored in the locked medication area of a care facility provided that:

a. The facility uses the solution only within the confines of the facility and under the orders of an authorized prescriber;

b. Upon use, the container is identified by resident name and is used exclusively for that resident;

c. The container is dated and initialed upon opening.

d. The solution is stored appropriately after opening according to facility policy and manufacturer labeling.

23.13(3) *Floor-stocked, nonprescription drug containers.* All nonprescription drugs for use within the facility shall be in appropriate containers and adequately labeled to identify, at a minimum, drug name and manufacturer, strength, lot number, and expiration date.

23.13(4) *Leave meds.* Labeling of prescription drugs for residents on leave from the facility for a period in excess of 24 hours shall comply with 657—subrule 6.10(1). The dispensing pharmacist shall be responsible for packaging and labeling leave meds in compliance with this subrule.

23.13(5) *Discharge meds.* Drugs authorized for a resident being discharged from the facility shall be labeled in compliance with 657—subrule 6.10(1) before the resident removes those drugs from the facility premises. The dispensing pharmacist shall be responsible for packaging and labeling discharge meds in compliance with this subrule.

[ARC 1961C, IAB 4/15/15, effective 5/20/15; ARC 3859C, IAB 6/20/18, effective 7/25/18]

657—23.14(124,155A) Provision of drugs to a facility for immunization or screening programs. A pharmacy may provide drugs to be used in the care facility for a health immunization or ongoing screening program, such as influenza vaccine, tuberculin skin test, or hepatitis-B.

23.14(1) *Labeling.* The pharmacy label shall be affixed so as not to obscure the manufacturer's label and shall include the following information.

- a. Identification of pharmacy;
- b. Name of facility;
- c. Name of biological or drug;
- d. Route of administration when necessary for clarification;
- e. Strength of biological or drug;
- f. Auxiliary labels as needed;
- g. Date dispensed.

23.14(2) *Influenza and pneumococcal vaccines.* A patient-specific medication order shall not be required prior to administration to an adult patient of influenza or pneumococcal vaccines pursuant to physician-approved facility policy and after the patient has been assessed for contraindications.

23.14(3) *Notification.* The facility shall submit to the provider pharmacy a listing of those residents or staff members who have been immunized utilizing vaccine from each vial supplied by the provider pharmacy.

[ARC 3859C, IAB 6/20/18, effective 7/25/18]

657—23.15(124,155A) Return and reuse of drugs and devices. A pharmacy shall not accept from a patient or facility for reuse or resale any drug or device unless, in the professional judgment of the pharmacist, the integrity of the drug or device has not in any way been compromised. Under no circumstances shall a pharmacist accept from a patient or facility any controlled substances except for reuse by the same patient. Prescription drugs, excluding controlled substances, dispensed in a unit dose dispensing system pursuant to 657—Chapter 22 may, however, be returned and reused as authorized in 657—subrule 22.1(6). No items of a personal contact nature which have been removed from the original package or container after dispensing shall be accepted for return, exchanged, or resold by any pharmacist.

[ARC 3859C, IAB 6/20/18, effective 7/25/18]

657—23.16(124,155A) Destruction of outdated and improperly labeled drugs. Rescinded ARC 3859C, IAB 6/20/18, effective 7/25/18.

657—23.17(124,155A) Accountability of controlled substances. Use of Schedule II controlled substances shall be documented. A committee or representative of the facility may also require that Schedule III, IV, or V controlled substances or any other drugs be accounted for on proof-of-use forms. Documentation shall include at a minimum:

1. Name of drug;
2. Dose;
3. Name of ordering prescriber;

4. Name of resident;
5. Date and time of administration to resident;
6. Identification of individual administering;
7. Documentation of destruction, return to the pharmacy, or other disposition of all unused portions of single doses including the signatures of two individuals, at least one of whom is a licensed health care professional.

[ARC 3859C, IAB 6/20/18, effective 7/25/18]

657—23.18(124,155A) Schedule II orders. Rescinded ARC 3859C, IAB 6/20/18, effective 7/25/18.

657—23.19(124,155A) Dispensing Schedule II controlled substances. A pharmacy that dispenses Schedule II controlled substances shall advise facility personnel that federal and state laws and regulations governing such drugs require that accurate records be kept of their administration or their ultimate disposition in compliance with rule 657—23.17(124,155A). The pharmacy shall further advise facilities that stored Schedule II substances shall be double-locked in accordance with rules of the Iowa department of inspections and appeals. The requirement for double-locking Schedule II controlled substances shall not apply to periods during which drugs are being administered to residents; however, these substances shall be secured during such administration periods.

657—23.20(124,155A) Partial filling of Schedule II controlled substances. A medication order for a Schedule II controlled substance for a resident in a long-term care facility (LTCF) may be filled in partial quantities to include individual dosage units. The pharmacist shall record on the written or electronic medication order that the patient is an “LTCF patient.” A medication order that is partially filled and does not contain the notation “LTCF patient” shall be deemed to have been filled in violation of the controlled substances Act.

23.20(1) Partial filling record. For each partial filling, the dispensing pharmacist shall record on the back of the medication order (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist.

23.20(2) Total dispensed. The total quantity of Schedule II controlled substances dispensed in all partial fillings shall not exceed the total quantity prescribed.

23.20(3) Duration. Schedule II medication orders for residents in a long-term care facility shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of the drug.

23.20(4) Requirements of computerized system. Information pertaining to current Schedule II medication orders for residents in a long-term care facility may be maintained in a computerized system if this system has the capability to permit:

a. Output (display and printout) of the original prescription number, date of issue, identification of prescribing individual practitioner, identification of resident, address of the long-term care facility, identification of the drug authorized (to include dosage form, strength and quantity), listing of the partial fillings that have been dispensed under each medication order, and the information required in this rule.

b. Immediate (real-time) updating of the medication order record each time a partial filling of the medication order is conducted.

c. Retrieval of partially filled Schedule II medication order information as required in rule 657—21.4(124,155A).

[ARC 9912B, IAB 12/14/11, effective 1/18/12]

657—23.21(124,155A) Disposal of previously dispensed controlled substances. Controlled substances dispensed to a resident in a care facility and subsequently requiring disposal due to discontinuance of the drug, death of the resident, or other reasons necessitating disposal shall be disposed of by one of the following methods. Controlled substances shall not be returned to a pharmacy for disposal.

23.21(1) *Disposal in the facility.* A licensed health care professional (pharmacist, registered nurse, licensed practical nurse) may dispose of controlled substances in witness of one other responsible adult. The professional disposing of the drug shall prepare and maintain a readily retrievable record of the disposition which shall be clearly marked to indicate the disposition of resident drugs. The record shall include, at a minimum, the following:

- a. Resident name and unique identification or number assigned by the dispensing pharmacy to the prescription;
- b. The name, strength, and dosage form of the substance;
- c. The quantity disposed of;
- d. The date the substance is disposed of;
- e. The signature or uniquely identifying initials or other unique identification of the professional and the witness;
- f. The name and address of the dispensing pharmacy or the dispensing practitioner.

23.21(2) *Authorized collection program within a facility.* Pharmacies registered with DEA as authorized collectors may install and manage a collection receptacle in a care facility for the purpose of disposal of unwanted medications, including prescription drugs and controlled substances, pursuant to federal regulations.

[ARC 0749C, IAB 5/29/13, effective 7/3/13; ARC 2408C, IAB 2/17/16, effective 3/23/16; ARC 3859C, IAB 6/20/18, effective 7/25/18]

These rules are intended to implement Iowa Code sections 124.301, 124.306, 124.308, 155A.2, 155A.13, 155A.15, 155A.21, 155A.27, 155A.28, 155A.33, 155A.35, and 155A.36.

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