CHAPTER 23
LONG-TERM CARE PHARMACY PRACTICE

657—23.1(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 http://deadiversion.usdoj.gov/drug_disposal/.

"Consultant pharmacist" in a long-term care facility means a pharmacist licensed to engage in the practice of pharmacy in this state who is responsible for developing, coordinating, and supervising pharmaceutical services in a long-term care facility on a regularly scheduled basis. A consultant pharmacist:

1. Reviews the distribution and storage of drugs and devices and assists facilities in establishing the policies and procedures for the distribution and storage of drugs and devices and makes appropriate recommendations to the facility and the provider pharmacist;
2. Monitors the therapeutic response and utilization of all drugs and devices prescribed for each resident. The following shall be used as minimum guidelines supplementing the pharmacist's professional expertise:

- Regulations and interpretive guidelines of the Centers for Medicare and Medicaid Services, if applicable;
- Rules of the Iowa department of inspections and appeals; and
- Other state rules and regulations;

3. Serves as a resource for pharmacy-related education services within the facility;
4. Participates in quality management of resident care in the facility;
5. Communicates with the provider pharmacist regarding areas of mutual concern and resolution thereof.

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

"Long-term care facility" or *"facility"* means:

1. A facility licensed by the Iowa department of inspections and appeals under Iowa Code chapter 135C or Iowa Code chapter 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.

"Long-term care pharmacy" or *"provider pharmacy"* means a hospital pharmacy, a general pharmacy, a limited use pharmacy, or a nonresident pharmacy in which drugs, chemicals, or poisons are prepared, compounded, dispensed, vended, distributed, or sold on a regular and recurring basis to or for the use of residents of a long-term care facility and from which related pharmacy services are delivered.

"Medication order," as used in these rules, means a written order from a practitioner or an oral 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 long-term care pharmacy or a provider pharmacy and who is responsible for supervising the accurate dispensing and proper delivery of drugs and devices to a long-term 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.

"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 a resident 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.
[**ARC 2408C**, IAB 2/17/16, effective 3/23/16]

657—23.2(124,155A) Applicability of rules. Nothing in these rules shall be deemed to constitute a waiver or abrogation of any of the provisions of board rules or other applicable provisions of state and federal laws and rules, nor should these rules be construed as authorizing or permitting any person not licensed as a pharmacist to engage in the practice of pharmacy.

657—23.3(124,155A) Freedom of choice. Pursuant to 657—subrule 8.11(5), no pharmacist or pharmacy shall participate in any agreement or plan that infringes on any resident's right to freedom of choice as to the provider of pharmacy services. A resident in a long-term care facility shall have a choice of long-term care pharmacy so long as the pharmacy's drug delivery system provides for the timely delivery of drugs compatible with the established system currently used by the facility. Determination of compatibility may consider medication administration, accessibility, and payment system.

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

1. Providing drugs pursuant to a medication order for an individual resident, properly labeled for that resident, as addressed in rule 657—22.1(155A) or 657—23.13(124,155A).
2. Dispensing drugs for residents of long-term care facilities consistent with the drug distribution system described in the facility's policies and procedures.
3. Affixing labels to each container of drugs for residents in long-term care facilities, in compliance with rule 657—22.1(155A), 657—23.13(124,155A), or 657—23.14(124,155A).
4. Maintaining records of all transactions of the long-term care pharmacy as may be required by law and maintaining accurate control over and accountability for all drugs and prescription devices.
5. Complying with a drug recall procedure, established pursuant to rule 657—8.3(155A), that protects the health and safety of residents including immediate discontinuation of any recalled drug or device and subsequent notification of the prescriber and director of nursing of the facility.
6. Providing 24-hour emergency service either directly or by contract with another pharmacy.
7. Reviewing patient profiles to ensure the appropriateness of therapy for that resident and the compatibility of the drug and dosage for that resident when processing new medication orders.
8. Providing sufficient and accurate information to facility staff regarding the appropriate administration and use of all dispensed drugs and devices.
9. Communicating with the consultant pharmacist and the facility regarding concerns and resolution thereof.

[**ARC 1961C**, IAB 4/15/15, effective 5/20/15]

657—23.5(124,155A) Emergency drugs. A supply of emergency drugs may be provided by one or more long-term care provider 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 one or more emergency boxes or stat drug boxes, a long-term care facility staffed by one or more persons licensed to administer drugs 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]

657—23.6(124,155A) Space, equipment, and supplies. Pursuant to rule 657—8.3(155A), each pharmacy serving a long-term care facility shall have adequate space, equipment, and supplies for the professional and administrative functions of the pharmacy and to meet the needs of the residents served. The pharmacy shall also comply with all reference, environment, and equipment requirements contained in rules 657—6.3(155A) and 657—8.5(155A).
[**ARC 1961C**, IAB 4/15/15, effective 5/20/15]

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 the long-term 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.

[**ARC 1961C**, IAB 4/15/15, effective 5/20/15]

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.

23.9(1) *Requirements.* New orders transmitted to the pharmacy for drugs for residents of the facility shall, at a minimum, contain resident name, drug name and strength, directions for use, date of order, and name of prescriber. Orders for Schedule II controlled substances shall comply with the requirements of rule 657—23.18(124,155A).

23.9(2) *Abbreviations.* Abbreviations or chemical symbols utilized in medication orders shall be only those abbreviations or symbols that are customarily used in the practice of medicine and pharmacy or those on a list of approved abbreviations developed by the appropriate committee or representative of the facility.

23.9(3) *Who may transmit medication orders.* An authorized prescriber or prescriber's agent or any person who is employed by a long-term care facility and who is authorized by the facility's policies and procedures may transmit to the long-term care pharmacy a medication order lawfully ordered by a practitioner authorized to prescribe drugs and devices. An order transmitted by the prescriber's agent shall include the agent's first and last names and title.

23.9(4) *Influenza and pneumococcal vaccines.* As authorized by federal law, a written or verbal patient-specific medication administration order shall not be required prior to administration to an adult patient of influenza and pneumococcal vaccines pursuant to physician-approved facility policy and after the patient has been assessed for contraindications. Administration shall be recorded in the patient's record. 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 9912B**, IAB 12/14/11, effective 1/18/12; **ARC 2197C**, IAB 10/14/15, effective 11/18/15]

657—23.10(124,155A) Stop orders. To ensure that drug orders are not continued inappropriately, the pharmacy's policies and procedures, established pursuant to rule 657—8.3(155A) and in consultation with the medical director and the appropriate committee or representative of the facility, shall include an automatic stop order policy. Drugs not specifically limited when ordered as to duration of therapy or number of doses shall be controlled by the automatic stop order policy in accordance with the status of the patient.
[**ARC 1961C**, IAB 4/15/15, effective 5/20/15]

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

23.11(1) *Labeling.* All prescription containers, other than those dispensed pursuant to rule 657—22.1(155A), 657—23.13(124,155A), or 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 pharmacy shall be responsible for affixing the correct label to the container. Long-term care facility personnel shall not be authorized to affix such a label to the drug container.

b. Direction change labels that notify long-term 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) and in subrule 23.9(4).

23.11(3) *Prescription containers.* All prescription containers, including but not limited to single unit, unit dose, and unit of issue containers utilized for distribution within a long-term care facility, shall meet minimum requirements as established by the United States Pharmacopoeia. When applicable, light-resistant packaging shall be used.

23.11(4) *Floor stock.* Prescription drugs, as defined by Iowa Code section 155A.3(37), shall not be floor-stocked in a long-term 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]

657—23.12 Reserved.

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

23.13(1) *Insulin, ophthalmics, otic preparations, biologicals, and other injectables for individual patients.* These drugs 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 licensed pharmacy may be stored in the locked medication area of a long-term 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.

23.13(3) *Floor-stocked, nonprescription drug containers.* All such nonprescription drugs intended for use within the facility shall be in appropriate containers and adequately labeled to identify, at a minimum, brand name or generic name and manufacturer, strength, lot number, and expiration date. An internal code that centrally references manufacturer and lot number may be utilized.

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]

657—23.14(124,155A) Labeling of biologicals and other injectables supplied to a facility. Labeling of biologicals and other injectables supplied to a facility for a health immunization or ongoing screening program, such as influenza vaccine, tuberculin skin test, or hepatitis-B, and intended for use in the facility, shall include the following information in addition to the manufacturer's label. The pharmacy label shall be affixed so as not to obscure the manufacturer's label.

1. Identification of pharmacy;
2. Name of facility;
3. Name of biological or drug;
4. Route of administration when necessary for clarification;
5. Strength of biological or drug;
6. Auxiliary labels as needed;
7. Date dispensed.

657—23.15(124,155A) Return and reuse of drugs and devices. Pharmacists and pharmacies shall not accept from residents or their agents for reuse or resale any drugs, prescribed drugs, chemicals, poisons or medical devices unless, in the professional judgment of the pharmacist, the integrity of the prescription drug has not in any way been compromised. Under no circumstances shall a pharmacist accept from a patient or patient's agent any controlled substances for return, exchange, or resale except to the same patient. Prescription drugs, excluding controlled substances, dispensed in unit dose, unit of issue, or single unit packaging pursuant to 657—22.1(155A) 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 sale shall be accepted for return, exchanged, or resold by any pharmacist.

657—23.16(124,155A) Destruction of outdated and improperly labeled drugs. The pharmacy, pursuant to rule 657—8.3(155A) and in consultation with a facility representative, shall have written policies and procedures to ensure that all discontinued, outdated, deteriorated, or improperly labeled drugs and all containers with worn, illegible or missing labels are destroyed or disposed of so as to render them unusable. Drugs shall be destroyed by means that will ensure protection against unauthorized possession or use.
[**ARC 1961C**, IAB 4/15/15, effective 5/20/15]

657—23.17(124,155A) Accountability of controlled substances.

23.17(1) *Proof of use.* Documentation of use of Schedule II controlled substances shall be upon proof-of-use forms. 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. Proof-of-use forms shall specify at a minimum:

a. Name of drug;
b. Dose;
c. Name of ordering prescriber;
d. Name of resident;
e. Date and time of administration to resident;
f. Identification of individual administering;
g. 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.

23.17(2) *Container requirement.* Any drug required to be counted and accounted for with proof-of-use forms shall be dispensed in a container that allows visual verification of quantity. Containers for solid oral doses must allow visual identification of individual doses and individual accountability.

657—23.18(124,155A) Schedule II orders. This rule shall not apply to Schedule II controlled substances orders in facilities that utilize a floor stock distribution system as provided in subrule 23.11(4). Schedule II controlled substances in all other facilities shall be dispensed only upon receipt of an electronic prescription prepared, transmitted, and received in compliance with DEA regulations for electronic prescriptions or an original written order signed by the prescribing individual practitioner or upon receipt of a facsimile transmission of an original written order signed by the prescribing individual practitioner pursuant to rule 657—21.15(124,155A). In emergency situations as defined in rule 657—10.26(124), Schedule II controlled substances may be dispensed in compliance with the requirements of rule 657—10.26(124) or rule 657—21.13(124,155A), as applicable. In all cases, any order for a Schedule II controlled substance shall specify the total quantity authorized by the prescriber.
[**ARC 9912B**, IAB 12/14/11, effective 1/18/12; **ARC 3345C**, IAB 9/27/17, effective 11/1/17]

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 long-term 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.* In facilities staffed by one or more persons licensed to administer drugs, 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.* Registrants registered with DEA to administer an authorized collection program may install and maintain a collection receptacle in a long-term care facility for the purpose of disposal of prescription drugs, including controlled substances, pursuant to federal regulations, which can be found at http://deadiversion.usdoj.gov/drug_disposal/.

[**ARC 0749C**, IAB 5/29/13, effective 7/3/13; **ARC 2408C**, IAB 2/17/16, effective 3/23/16]

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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