

CHAPTER 7
HOSPITAL PHARMACY PRACTICE
[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 12]

Chapter rescission date pursuant to Iowa Code section 17A.7: 1/1/28

657—7.1(155A) Purpose and scope. Hospital pharmacy means and includes a pharmacy licensed by the board and located within any hospital, health system, institution, or establishment which maintains and operates organized facilities for the diagnosis, care, and treatment of illnesses to which patients may or may not be admitted for overnight stay at the facility. A hospital is a facility licensed pursuant to Iowa Code chapter 135B. This chapter does not apply to a pharmacy located within such a facility for the purpose of providing outpatient prescriptions. A pharmacy providing outpatient prescriptions is and shall be licensed as a general pharmacy subject to the requirements of 657—Chapter 6. The requirements of these rules for hospital pharmacy practice apply to all hospitals, regardless of size or type, and are in addition to the requirements of 657—Chapter 8 and other rules of the board relating to services provided by the pharmacy. [ARC 9911B, IAB 12/14/11, effective 1/18/12]

657—7.2(155A) Pharmacist in charge. One professionally competent, legally qualified pharmacist in charge in each pharmacy shall be responsible for, at a minimum, the responsibilities identified in rule 657—8.3(155A). Where 24-hour operation of the pharmacy is not feasible, a pharmacist shall be available on an “on call” basis. [ARC 8673B, IAB 4/7/10, effective 6/1/10; ARC 1961C, IAB 4/15/15, effective 5/20/15]

657—7.3(155A) Reference library. A pharmacy shall maintain a reference library which is either printed or computer-accessed and which adequately meets the needs of the services provided and patients served. Examples of such references include:

1. A reference including all pertinent Iowa laws, rules, and regulations that impact the pharmacy’s practice.
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 drug information reference.
5. A drug equivalency reference.
6. An injectable-drug compatibility reference.
7. A drug identification reference to enable identification of drugs brought into the facility by patients.
8. The readily accessible telephone number of a poison control center that serves the area.
9. Additional references relating to specific patient populations served, such as pediatrics or geriatrics, or disease states treated, such as oncology or infectious disease.

[ARC 2196C, IAB 10/14/15, effective 11/18/15; ARC 4267C, IAB 1/30/19, effective 3/6/19]

657—7.4 Reserved.

657—7.5(124,155A) Security. The pharmacy shall be located in an area or areas that facilitate the provision of services to patients and shall be integrated with the facility’s communication and transportation systems. The following conditions must be met to ensure appropriate control over drugs and chemicals in and under the control of the pharmacy:

7.5(1) Pharmacy department security. Policies and procedures shall identify measures to ensure the security of the pharmacy department, including provisions for effective control against theft of, diversion of, or unauthorized access to drugs or devices, controlled substances, records for such drugs, and patient records, including when the pharmacist is absent from the pharmacy department or absent from the facility pursuant to rule 657—7.6(155A).

7.5(2) *Security outside the pharmacy department.* Policies and procedures shall identify measures to ensure security in areas outside the pharmacy department where drugs, including controlled substances, devices, drug records, and patient records are maintained or stored, including provisions for effective control against theft of, diversion of, or unauthorized access to such drugs and records.

7.5(3) *Authorized collection program.* Receptacles that are located in the hospital for the authorized collection of controlled substances shall be secured pursuant to 657—Chapter 10 and federal regulations for disposal of controlled substances.

7.5(4) *System security.* Electronic systems shall be secured to prevent unauthorized access. System login or access credentials issued to an authorized system user shall not be shared with or disclosed to any other individual.

[ARC 8673B, IAB 4/7/10, effective 6/1/10; ARC 9408B, IAB 3/9/11, effective 4/13/11; ARC 1308C, IAB 2/5/14, effective 3/12/14; ARC 2408C, IAB 2/17/16, effective 3/23/16; ARC 4267C, IAB 1/30/19, effective 3/6/19]

657—7.6(155A) Pharmacist absence.

7.6(1) *Pharmacist absent from the pharmacy department.* A pharmacy's policies and procedures shall identify how the pharmacy will operate and be secured to prevent unauthorized access during times when the pharmacist may be absent from the pharmacy department but not absent from the facility. The policies and procedures shall also identify authorized activities of pharmacy staff in the pharmacy department during the absence of the pharmacist from the department in compliance with rules of the board.

a. Remote pharmacy services. Pursuant to rule 657—7.7(155A), the pharmacy may utilize the services of a remote pharmacist or pharmacy to provide pharmacist services to assist the pharmacy department while the on-site pharmacist is absent from the pharmacy department, such as when participating in clinical activities with facility staff and patients.

b. Certified pharmacy technicians. Pursuant to the pharmacy's policies and procedures, a certified pharmacy technician may be granted access to the pharmacy department to perform authorized technical functions. In the absence of a pharmacist, a certified pharmacy technician may only dispense, deliver, or distribute a drug, including a compounded preparation and controlled substance, when the drug is verified by a pharmacist, including by a remote pharmacist, except as authorized in an approved technician product verification program. A certified pharmacy technician may assist a licensed health care professional in locating a drug to meet the emergent needs of a patient but shall not provide final verification of the accuracy of the drug product obtained.

c. Pharmacy support persons. Pursuant to the pharmacy's policies and procedures, a pharmacy support person may be granted access to the pharmacy department to perform authorized nontechnical functions.

d. Licensed health care professionals. Pursuant to the pharmacy's policies and procedures, a licensed health care professional may be granted access to the pharmacy department to meet the emergent needs of a patient. A licensed health care professional may utilize the assistance of a certified pharmacy technician to locate a drug but shall not rely on the technician to verify the accuracy of the drug product obtained.

7.6(2) *Pharmacy department closed.* When the pharmacist is absent from the facility, the pharmacy department shall be closed and secured to prevent unauthorized access. The pharmacist in charge shall identify in policies and procedures the facility and pharmacy staff, by title or designation, who are authorized access to the pharmacy department and the specific activities that are authorized.

a. Remote pharmacy services. Pursuant to rule 657—7.7(155A), the pharmacy may utilize the services of a remote pharmacist or pharmacy to provide pharmacist services to the facility when the pharmacy is closed.

b. Certified pharmacy technicians. Pursuant to the pharmacy's policies and procedures, a certified pharmacy technician may be granted access to the pharmacy department to perform authorized technical functions. In the absence of a pharmacist, a certified pharmacy technician may only dispense, deliver, or distribute a drug, including a compounded preparation and controlled substance, when the drug is verified by a pharmacist, including by a remote pharmacist. During each period of time the certified pharmacy technician is working in the pharmacy without pharmacist supervision, the technician shall document the time worked and activities performed. The documentation shall be periodically reviewed by the pharmacist in charge. A certified pharmacy technician may assist a licensed health care professional in locating a drug

to meet the emergent needs of a patient but shall not provide the final verification of the accuracy of the drug obtained.

c. Pharmacy support persons. Pursuant to the pharmacy's policies and procedures, a pharmacy support person may be granted access to the pharmacy department to perform authorized nontechnical functions. During each period of time the pharmacy support person is working in the pharmacy without pharmacist supervision, the support person shall document the time worked and activities performed. The documentation shall be periodically reviewed by the pharmacist in charge.

d. Licensed health care professionals. Pursuant to the pharmacy's policies and procedures, a licensed health care professional may be granted access to the pharmacy department to meet the emergent needs of a patient. A licensed health care professional may utilize the assistance of a certified pharmacy technician to locate a drug but shall not rely on the technician to verify the accuracy of the drug product obtained. The pharmacy shall maintain documentation of such access and activities.

This rule is intended to implement Iowa Code sections 124.301, 147.76, 147.107, and 155A.33.
[ARC 4267C, IAB 1/30/19, effective 3/6/19; ARC 5007C, IAB 3/25/20, effective 4/29/20]

657—7.7(155A) Verification by remote pharmacist. A hospital pharmacy may contract with an Iowa-licensed pharmacy or pharmacist for remote pharmacist services, including medication order entry and review, final product verification, and provision of drug information. Pharmacies and pharmacists entering into a contract or agreement pursuant to this rule shall comply with the following requirements:

7.7(1) Nonsupplanting service. A contract or agreement for remote pharmacist services shall not relieve the hospital pharmacy from employing or contracting with a pharmacist to provide routine pharmacy services within the facility. The activities authorized by this rule are intended to supplement on-site hospital pharmacy services and are not intended to eliminate the need for an on-site hospital pharmacy or pharmacist. The activities authorized by this rule are intended to increase the availability of the pharmacist for involvement in clinical patient care activities when the pharmacy is open or to continue the provision of pharmacy services when the pharmacy is closed. The hospital pharmacy shall maintain records that demonstrate the directing of pharmacist activities to additional clinical patient care activities, and those records shall be available for inspection by the board or its authorized agent.

7.7(2) Hospital-staff pharmacist. Nothing in this rule shall prohibit a pharmacist employed by or contracting with a hospital pharmacy for on-site services from also providing remote pharmacist services identified in this chapter in compliance with this rule.

7.7(3) Licenses required. A pharmacy or pharmacist contracting with a hospital pharmacy to provide services pursuant to this rule shall maintain with the board a current Iowa pharmacy license or pharmacist license, respectively. A remote pharmacist providing pharmacy services as an employee or agent of a contracting pharmacy pursuant to this rule shall be licensed to practice pharmacy in Iowa.

7.7(4) Remote access requirements. A pharmacist providing services from a remote location shall:

- a.* Have secure electronic access to the hospital's patient information system on which the pharmacist has been adequately trained,
- b.* Have access to the patient's health care team to discuss any concerns identified during the pharmacist's review of the patient's information or medication order,
- c.* Have secure access to any other electronic systems the pharmacist would otherwise have access to in the facility,
- d.* Have access to sufficient references to adequately meet the needs of the patients served, and
- e.* When involved in review or verification, be identified, by name or unique identifier and function performed, on the drug or device order.

[ARC 9408B, IAB 3/9/11, effective 4/13/11; ARC 0502C, IAB 12/12/12, effective 1/16/13; ARC 4267C, IAB 1/30/19, effective 3/6/19]

657—7.8(124,126,155A) Drug distribution and control. Policies and procedures governing drug distribution and control shall be established pursuant to rule 657—8.3(155A) with input from other involved hospital staff such as physicians and nurses, from committees such as the pharmacy and therapeutics committee or its equivalent, and from any related patient care committee. It is essential that the pharmacist in charge or designee routinely be available to or on all patient care areas to establish rapport

with the personnel and to become familiar with and contribute to medical and nursing procedures relating to drugs.

7.8(1) Drug preparation. Control and adequate quality assurance procedures needed to ensure that patients receive the correct drugs at the proper times shall be established pursuant to rule 657—8.3(155A).

a. Hospitals shall utilize a unit dose dispensing system pursuant to rule 657—22.1(155A). All drugs dispensed by the pharmacy for administration to patients shall be in single unit or unit dose packages if practicable unless the dosage form or drug delivery device makes it impracticable to package the drug in a unit dose or single unit package.

(1) Established policies and procedures shall identify situations when drugs may be dispensed in other than unit dose or single unit packages outside the unit dose dispensing system.

(2) The need for nurses to manipulate drugs prior to their administration shall be minimized.

b. All sterile and nonsterile compounded products shall be prepared in conformance with 657—Chapter 20.

7.8(2) Medication orders. Except to meet the emergent needs of a patient, no drug or device shall be dispensed or made available for patient administration prior to the issuance of a valid medication order and appropriate pharmacist review.

a. Verbal order. The use of verbal orders shall be minimized. All verbal orders shall be read back to the prescriber, and the read back shall be documented with or on the order.

b. Written order not entered by prescriber. If an individual other than the prescriber enters a medication order into an electronic medical record system from an original written medication order, a pharmacist shall review and verify the entry against the original written order before the drug is dispensed or made available for administration except for emergency use, when the pharmacy is closed, or as provided in rule 657—7.7(155A).

c. Order entered when pharmacy closed. When the pharmacy is closed and remote pharmacist services are not available, a registered nurse or pharmacist may enter a medication order into an electronic medical record system for the purpose of creating an electronic medication administration record and, except when a pharmacist entered the order, a pharmacist shall verify the entry against the original written medication order, if such written order exists, as soon as practicable.

d. Abbreviations and chemical symbols on orders. The use of abbreviations and chemical symbols on medication orders shall be discouraged but, if used, shall be limited to abbreviations and chemical symbols approved by the appropriate patient care committee.

7.8(3) Stop order. A policy concerning stop orders shall be established to ensure that medication orders are not inappropriately continued.

7.8(4) Emergency drug supplies and floor stock. Pursuant to policies and procedures, supplies of drugs for use in medical emergencies shall be immediately available. All drug storage areas within the facility shall be routinely inspected to ensure that no outdated or unusable items are available for administration and that all stock items are properly labeled and stored.

7.8(5) Disaster services. The pharmacy shall be prepared to provide drugs and pharmaceutical services in the event of a disaster affecting the availability of drugs or internal access to drugs or access to the pharmacy.

7.8(6) Drugs brought into the facility. Established policies and procedures shall determine those circumstances when patient-owned drugs brought into the facility may be administered to the patient and shall identify procedures governing the use and security of drugs brought into the facility. Procedures shall address identification of the drug and methods for ensuring the integrity of the product prior to permitting its use. The use of patient-owned drugs shall be minimized to the greatest extent possible.

7.8(7) Samples. The use of drug samples within the institution shall be eliminated to the extent possible. Sample use is prohibited for hospital inpatient use. For the purposes of this subrule, “samples” shall not include initiation doses provided by a manufacturer’s long-acting antipsychotic medication initiation program.

7.8(8) Investigational drugs. If investigational drugs are used in the facility:

a. A pharmacist shall be a member of the institutional review board or its equivalent.

b. The pharmacy shall be responsible, in cooperation with the principal investigator, for providing information about investigational drugs used in the facility and for the distribution and control of those drugs.

7.8(9) Hazardous drugs and chemicals. Policies and procedures for handling drugs and chemicals that are known occupational hazards shall be established pursuant to rule 657—8.3(155A). The procedures shall maintain the integrity of the drug or chemical and protect facility personnel.

7.8(10) Leave and discharge meds. Labeling of medications for a patient on leave from the facility for a period in excess of 24 hours or being discharged from the facility shall comply with 657—subrule 6.10(1).

7.8(11) Own-use outpatient prescriptions. If the hospital pharmacy dispenses own-use outpatient prescriptions, the pharmacist shall comply with all requirements of 657—Chapter 6 except rule 657—6.1(155A).

7.8(12) Influenza and pneumococcal vaccines. As authorized by federal law, a patient-specific medication 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 medical record.

7.8(13) Accountability of stock supply. An individual who administers a controlled substance from a non-patient-specific stock supply in a facility shall personally document on a separate readily retrievable record system each dose administered, wasted, or returned to the pharmacy. Such documentation shall not be delegated to another individual. Wastage documentation shall include the signature or unique electronic signature or identification of a witnessing licensed health care practitioner. Distribution records for non-patient-specific floor-stocked controlled substances shall include the following information:

- a. Patient's name;
- b. Prescriber who ordered the drug;
- c. Drug name, strength, dosage form, and quantity;
- d. Date and time of administration;
- e. Signature or unique electronic signature of the individual administering the controlled substance;
- f. Returns to the pharmacy;
- g. Waste, which is required to be witnessed and cosigned by another licensed health care practitioner.

[ARC 8170B, IAB 9/23/09, effective 10/28/09; ARC 9911B, IAB 12/14/11, effective 1/18/12; ARC 1961C, IAB 4/15/15, effective 5/20/15; ARC 2194C, IAB 10/14/15, effective 11/18/15; ARC 2197C, IAB 10/14/15, effective 11/18/15; ARC 4267C, IAB 1/30/19, effective 3/6/19]

657—7.9(124,155A) Drug information. Established policies and procedures shall include the provision to the facility's staff and patients of accurate, comprehensive information about drugs and their use. The pharmacy shall serve as the facility's center for drug information.

[ARC 1961C, IAB 4/15/15, effective 5/20/15; ARC 4267C, IAB 1/30/19, effective 3/6/19]

657—7.10(124,155A) Ensuring rational drug therapy. An important aspect of pharmaceutical services is that of maximizing rational drug use. Policies and procedures for ensuring the quality of drug therapy shall be established pursuant to rule 657—8.3(155A). For the purpose of this rule, "professional pharmacy staff" means the professional employees of the pharmacy, including pharmacists, pharmacy technicians, and pharmacist-interns.

7.10(1) Patient profile. The pharmacy shall maintain for each patient receiving care at the hospital a patient profile, to include but not be limited to drug history. Sufficient patient information to ensure meaningful and effective patient care shall be collected, maintained, and reviewed by professional pharmacy staff pursuant to policies and procedures. Appropriate clinical information about patients shall be available and accessible to the pharmacist for use in daily practice. Upon review of a patient's current clinical profile, the pharmacist shall directly communicate any suggested changes to the patient's health care team.

7.10(2) Adverse drug events. Established policies and procedures shall include a mechanism for the reporting of adverse drug events that occur in the facility which events are reviewed by the facility's established quality control committee. The pharmacist shall be informed of all reported adverse drug events

occurring in the facility. Adverse drug events include but are not limited to adverse drug reactions and medication errors.

[ARC 1961C, IAB 4/15/15, effective 5/20/15; ARC 4267C, IAB 1/30/19, effective 3/6/19]

657—7.11(124,126,155A) Outpatient services. No prescription drugs shall be dispensed from the hospital pharmacy to patients treated in a hospital outpatient setting. If a need is established for the dispensing of a prescription drug to an outpatient, a prescription shall be issued to be filled at a pharmacy of the patient's choice.

7.11(1) Definitions. For the purposes of this rule, the following definitions shall apply:

“Emergency department patient” means a patient who is examined and evaluated in the emergency department.

“Outpatient” means a patient who was examined and evaluated by a prescriber who determined the patient's need for the administration of a drug or device, when the patient presents to the hospital outpatient setting with a prescription or order for administration of a drug or device. “Outpatient” does not include an emergency department patient.

“Outpatient medication order” means an order issued by a prescriber pursuant to rules of the board for administration of a drug or device. An outpatient medication order may authorize continued or periodic administration of a drug or device for a period of time and frequency determined by the prescriber or by hospital policy, not to exceed legal limits for the refilling of a prescription drug order.

7.11(2) Administration in the outpatient setting. Drugs shall be administered only to outpatients who have been examined and evaluated by a prescriber who determined the patient's need for the drug therapy ordered.

a. Accountability. Established policies and procedures shall include a system of drug control and accountability in the outpatient setting. The system shall ensure accountability of drugs incidental to outpatient nonemergency therapy or treatment. Drugs shall be administered only in accordance with the system.

b. Controlled substances. Controlled substances maintained in the outpatient setting are kept for use by or at the direction of prescribers for the nonemergency therapy or treatment of outpatients. In order to have a controlled substance administered, a patient shall be examined in the outpatient setting or in an alternate practice setting or office by a prescriber who shall determine the patient's need for the drug. If the patient is examined in a setting other than the outpatient setting, the prescriber shall issue a prescription or order for administration of the drug in the hospital outpatient setting.

c. Outpatient medication orders. A prescriber may authorize, by outpatient medication order, the periodic administration of a drug to an outpatient.

(1) Schedule II controlled substance. An outpatient medication order for administration of a Schedule II controlled substance shall be issued pursuant to federal regulation and board rules and, except as provided in rule 657—10.29(124) regarding the issuance of multiple Schedule II prescriptions, may authorize the administration of an appropriate amount of the prescribed substance for a period not to exceed 90 days from the date ordered.

(2) Schedule III, IV, or V controlled substance. An outpatient medication order for administration of a Schedule III, IV, or V controlled substance shall be issued pursuant to federal regulation and board rules and may be authorized for a period not to exceed six months from the date ordered.

(3) Noncontrolled substance. An outpatient medication order for administration of a noncontrolled prescription drug may be authorized for a period not to exceed 18 months from the date ordered.

7.11(3) Samples. If the use of drug samples is permitted for hospital outpatients, that use of samples shall be controlled and the samples shall be distributed through the pharmacy or through a process developed in cooperation with the pharmacy and the facility's appropriate patient care committee, subject to oversight by the pharmacy.

[ARC 8909B, IAB 6/30/10, effective 8/4/10; ARC 0243C, IAB 8/8/12, effective 9/12/12; ARC 1961C, IAB 4/15/15, effective 5/20/15; ARC 3345C, IAB 9/27/17, effective 11/1/17; ARC 4267C, IAB 1/30/19, effective 3/6/19]

657—7.12(124,126,155A) Drugs in the emergency department. Drugs maintained in the emergency department are kept for use by or at the direction of prescribers in the emergency department. Drugs shall

be administered or dispensed only to emergency department patients. For the purposes of this rule, “emergency department patient” means a patient who is examined and evaluated in the emergency department and includes the partner or partners of a patient treated pursuant to Iowa Code section 139A.41.

7.12(1) *Accountability.* Established policies and procedures shall include a system of drug control and accountability in the emergency department. The system shall identify drugs of the nature and type to meet the emergency needs of patients. Drugs shall be administered or dispensed only in accordance with the system.

7.12(2) *Controlled substances.* Controlled substances maintained in the emergency department are kept for use by or at the direction of prescribers in the emergency department.

a. In order to receive a controlled substance, a patient shall be examined in the emergency department by a prescriber who shall determine the need for the drug. It is not permissible under state and federal regulations for a prescriber to see a patient outside the emergency department setting, or talk to the patient on the telephone, and then proceed to call the emergency department and order the administration of a stocked controlled substance upon the patient’s arrival at the emergency department except as provided in paragraph 7.12(2) “*c*” or “*d*.”

b. A prescriber may authorize, without again examining the patient, the administration of additional doses of a previously authorized drug to a patient presenting to the emergency department within 24 hours of the patient’s examination and treatment in the emergency department.

c. In an emergency situation when a health care practitioner authorized to prescribe controlled substances is not available on site, and regardless of the provisions of paragraph 7.12(2) “*a*,” the emergency department nurse may examine the patient in the emergency department and contact the on-call prescriber. The on-call prescriber may then authorize the nurse to administer a controlled substance to the patient pending the arrival of the prescriber at the emergency department. As soon as possible, the prescriber shall examine the patient in the emergency department and determine the patient’s further treatment needs.

d. In an emergency situation when a health care practitioner authorized to prescribe controlled substances examines a patient in the prescriber’s office and determines a need for the administration of a controlled substance, and regardless of the provisions of paragraph 7.12(2) “*a*,” the prescriber may direct the patient to present to the emergency department for the administration of a controlled substance for which the prescriber has issued a prescription in compliance with federal regulation and board rules. As soon as possible, the prescriber shall examine the patient in the emergency department and determine the patient’s further treatment needs.

7.12(3) *Drug dispensing.* Only a pharmacist or prescriber may dispense any drugs to an emergency department patient pursuant to the provisions of this rule.

a. Responsibility. Pursuant to rule 657—8.3(155A), policies and procedures shall be established to ensure the accuracy and labeling of prepackaged drugs and accurate records of dispensing of drugs from the emergency department shall be maintained.

(1) Except as provided in subrule 7.12(4), drugs dispensed to an emergency department patient may be dispensed in quantities not to exceed a 72-hour supply or the minimum quantity in suitable containers, except that an authorized supply of a drug provided through the department of public health may be dispensed for the treatment of a victim of sexual assault. Prepackaged drugs shall be prepared pursuant to the requirements of rule 657—22.3(126).

(2) Drugs dispensed pursuant to this paragraph shall be appropriately labeled as required in paragraph 7.12(3) “*b*,” including necessary auxiliary labels.

b. Prescriber responsibility. Except as provided in subrule 7.12(4), a prescriber who authorizes the dispensing of a prescription drug to an emergency department patient is responsible for the accuracy of the dispensed drug and for the accurate completion of label information pursuant to this paragraph, including when any portion of the dispensing process is delegated to a licensed nurse under the supervision of the prescriber.

(1) Except as provided in subrule 7.12(4), at the time of delivery of the drug the prescriber shall be responsible for ensuring that the dispensing container bears a label with at least the following information:

1. Name and address of the hospital;
2. Date dispensed;

3. Name of prescriber;
4. Name of patient, except when the drug is dispensed for one or more unnamed partners receiving expedited partner therapy pursuant to Iowa Code section 139A.41;
5. Directions for use; and
6. Name, quantity, and strength of drug.

(2) Except as provided in subrule 7.12(4), the prescriber, or a licensed nurse under the supervision of the prescriber, shall give the appropriately labeled, packaged drug to the patient or patient's caregiver. The prescriber, or a licensed nurse under the supervision of the prescriber, shall explain the correct use of the drug and shall explain to the patient that the dispensing is for an emergency or starter supply of the drug. If additional quantities of the drug are required to complete the needed course of treatment, the prescriber shall issue a prescription for the additional quantities to be filled at a pharmacy of the patient's choice.

7.12(4) Use of an outpatient point-of-care automated dispensing system (OPCADS). A hospital located in an area of the state where 24-hour outpatient pharmacy services are not available within 15 miles of the hospital may utilize an outpatient point-of-care automated dispensing system (OPCADS) in the emergency department only as provided by this subrule. For the purpose of this rule, an OPCADS is a secure dispensing system which contains prepackaged medications verified by authorized pharmacy personnel for dispensing to a patient upon issuance of a valid prescription by a prescriber. The OPCADS shall be owned by the facility, shall be operated under the facility's hospital pharmacy license, shall not be issued a separate general or limited use pharmacy license, and shall not provide any financial incentive for use to any prescriber employed or under contract with the emergency department.

a. Persons with access to the OPCADS for the purposes of stocking, inventory, and monitoring shall be limited to pharmacists, pharmacy technicians, and pharmacist-interns.

b. The OPCADS shall be used only in the emergency department for the benefit of patients examined or treated in the emergency department when the benefit to the patient outweighs the burden on the patient to obtain the medication elsewhere.

c. The OPCADS shall be located in a secure and professionally appropriate environment.

d. The stock of drugs maintained and dispensed utilizing the OPCADS shall be limited to acute care drugs provided in appropriate quantities for a 72-hour supply or the minimum commercially available package size, except that antimicrobials may be dispensed in a quantity to provide the full course of therapy.

e. Drugs dispensed utilizing the OPCADS shall be appropriately labeled as provided in 657—paragraphs 6.10(1)“a” through “g.”

f. Prior to authorizing the dispensing of a drug utilizing the OPCADS, the prescriber shall offer to issue the patient a prescription that may be filled at a pharmacy of the patient's choice.

g. During consultation with the patient or the patient's caregiver, the prescriber or licensed nurse under the supervision of the prescriber shall clearly explain the appropriate use of the drug supplied. If additional quantities of the drug are required to complete the needed course of treatment, the prescriber shall issue a prescription for the additional quantity to be filled at a pharmacy of the patient's choice.

h. The pharmacy shall, in conjunction with the emergency department, implement policies and procedures to ensure that a patient utilizing the OPCADS has been positively identified.

[ARC 8909B, IAB 6/30/10, effective 8/4/10; ARC 1961C, IAB 4/15/15, effective 5/20/15; ARC 4267C, IAB 1/30/19, effective 3/6/19; ARC 4903C, IAB 2/12/20, effective 3/18/20]

657—7.13(124,155A) Records. Every record required to be kept under this chapter or other board rules or under Iowa Code chapters 124 and 155A shall be kept by the pharmacy and be available for inspection and copying by the board or its authorized agent for at least two years from the date of such record unless a longer retention period is specified for the particular record.

7.13(1) Medication order information. Each original medication order contained in inpatient records shall include the following information:

- a.* Patient name and identification number;
- b.* Drug name, strength, and dosage form;
- c.* Directions for use;
- d.* Date ordered;

e. Prescriber's signature or electronic signature or that of the prescriber's authorized agent.

7.13(2) *Medication order maintained.* The original medication order shall be maintained with the medication administration record in the medical records of the patient following discharge.

7.13(3) *Documentation of drug administration.* Each dose of medication administered shall be properly recorded in the patient's medical record.

7.13(4) *Storage of records.* Original hard-copy records shall be maintained by the pharmacy for a minimum of two years from the date of the record in accordance with this subrule.

a. Records shall be maintained within the pharmacy department for a minimum of 12 months, except as provided herein. Pharmacy records less than 12 months old may be stored in a secure storage area outside the pharmacy department, including at a remote location, if the pharmacy has retained an electronic copy of the records in the pharmacy that is immediately available and if the original records are available within 72 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

b. Records more than 12 months old may be maintained in a secure storage area outside the pharmacy department, including at a remote location, if the records are retrievable within 72 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

[ARC 4267C, IAB 1/30/19, effective 3/6/19; ARC 5007C, IAB 3/25/20, effective 4/29/20]

These rules are intended to implement Iowa Code sections 124.301, 124.303, 124.306, 124.308, 126.10, 126.11, 155A.6A, 155A.6B, 155A.7, 155A.13, 155A.15, 155A.27, 155A.28, 155A.31 through 155A.36, 155A.38, 155A.41, 155A.43, and 155A.44.

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