

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

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 human illnesses to which persons 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.

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 items identified in this rule. A part-time pharmacist in charge has the same obligations and responsibilities as a full-time pharmacist in charge. Where 24-hour operation of the pharmacy is not feasible, a pharmacist shall be available on an “on call” basis. The pharmacist in charge, at a minimum, shall be responsible for:

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 and sufficient to ensure adequate levels of quality patient care services. Drug dispensing by nonpharmacists shall be minimized and eliminated wherever possible.
3. Ensuring the availability of any equipment and references necessary for the particular practice of pharmacy.
4. Ensuring that a pharmacist performs therapeutic drug monitoring and drug use evaluation.
5. Ensuring that a pharmacist provides drug information to other health professionals and to patients.
6. Dispensing drugs to patients, including the packaging, preparation, compounding, and labeling functions performed by pharmacy personnel.
7. Delivering drugs to the patient or the patient’s agent.
8. Ensuring that patient medication records are maintained as specified in rule 7.10(124,155A).
9. Training pharmacy technicians and supportive personnel.
10. Ensuring adequate and appropriate pharmacist oversight and supervision of pharmacy technicians and supportive personnel.
11. Procuring and storing prescription drugs and devices and other products dispensed from the pharmacy.
12. Distributing and disposing of drugs from the pharmacy.
13. 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.
14. Establishing and maintaining effective controls against the theft or diversion of prescription drugs, controlled substances, and records for such drugs.
15. Preparing a written operations manual governing pharmacy functions; periodically reviewing and revising those policies and procedures to reflect changes in processes, organization, and other pharmacy functions; and ensuring that all pharmacy personnel are familiar with the contents of the manual.
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.

657—7.3(155A) Reference library. References may be printed or computer-accessed. A reference library shall be maintained which includes, as 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. 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 as may be necessary for the pharmacist to adequately meet the needs of the patients served. For example, the treatment of pediatric patients and oncology patients would require additional references unique to those specialties.

657—7.4 and 7.5 Reserved.

657—7.6(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 the pharmacy:

7.6(1) Pharmacist responsibility. Each pharmacist, while on duty, shall be responsible for the security of the pharmacy area, 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 as provided in 657—Chapter 21. Policies and procedures shall identify the minimum amount of time that a pharmacist is available at the hospital pharmacy.

7.6(2) Access when pharmacist absent. When the pharmacist is absent from the facility, the pharmacy is closed. Policies and procedures shall be established that identify who will have access to the pharmacy when the pharmacy is closed and the procedures to be followed for obtaining drugs, devices, and chemicals to fill an emergent need during the pharmacist's absence.

a. The pharmacist in charge may designate pharmacy technicians who may be present in the pharmacy to perform technical and nontechnical functions designated by the pharmacist in charge. Activities identified in paragraph “*d*” of this subrule may not be performed when the pharmacy is closed.

b. If the pharmacist in charge has authorized the presence in the pharmacy of a pharmacy technician to perform designated functions when the pharmacy is closed, the technician may assist another authorized, licensed health care professional to locate a drug or device pursuant to an emergent need. The pharmacy technician may not dispense or deliver the drug, chemical, or device to the licensed health care professional. The licensed health care professional shall comply with established policies and procedures for obtaining drugs, devices, and chemicals when the pharmacy is closed. The licensed health care professional shall not ask or expect the pharmacy technician to verify that the appropriate drug, chemical, or device has been obtained from the pharmacy.

c. A pharmacy technician who is present in the pharmacy when the pharmacy is closed shall prepare and maintain in the pharmacy a log identifying each period of time that the technician worked in the pharmacy while the pharmacy was closed and identifying each activity performed during that time period. Each entry shall be dated and each daily record shall be signed by the pharmacy technician who prepared the record. The log shall be periodically reviewed by the pharmacist in charge.

d. Activities which shall not be performed by a pharmacy technician when the pharmacist is absent from the facility include:

(1) Dispensing, delivering, or distributing any prescription drugs or devices to patients or others, including health care professionals, prior to pharmacist verification. Verification by a nurse or other licensed health care professional shall not supplant verification by a pharmacist.

(2) Providing the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order.

(3) Conducting prospective drug use review or evaluating a patient's medication record for purposes identified in rule 657—8.21(155A).

(4) Providing patient counseling, consultation, or drug information.

(5) Making decisions that require a pharmacist's professional judgment such as interpreting or applying information.

(6) Preparing compounded drug products for immediate administration by other hospital staff or health care professionals without verification by a pharmacist.

7.6(3) *Locked areas.* All pharmacy areas where drugs or devices are maintained or stored and where a pharmacist is not continually present shall be locked.

7.6(4) *Verification by pharmacist.* When the pharmacy is open, patient-specific drugs or devices shall not be distributed prior to the pharmacist's final verification and approval.

7.6(5) *Drugs or devices in patient care areas.* Drugs or devices maintained or stored in patient care areas shall be in locked storage unless the patient care unit is staffed by health care personnel and the medication area is visible to staff at all times.

657—7.7(155A) Verification by pharmacist when pharmacy is closed. A hospital pharmacy may contract with another pharmacy for remote pharmacist preview and verification of patient-specific drugs or devices ordered for a patient when the hospital pharmacy is closed. Contracted services may include pharmacist order entry pursuant to subrule 7.8(3). Pharmacies 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 hospital pharmacy services when the pharmacy is closed and are not intended to eliminate the need for an on-site hospital pharmacy or pharmacist.

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 preview and verification of patient-specific drugs or devices ordered for a patient when the hospital pharmacy is closed. A pharmacist previewing and verifying drug or device orders from a remote location shall have access to patient information pursuant to subrule 7.7(4) or 7.7(5), shall have access to the prescriber as provided in subrule 7.7(6), and shall be identified on the drug or device order as provided in subrule 7.7(7).

7.7(3) *Licenses required.* A pharmacy contracting with a hospital pharmacy to provide services pursuant to this rule shall maintain with the board a current Iowa pharmacy license. 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) *Electronic access to patient information.* The remote pharmacist shall have secure electronic access to the hospital pharmacy's patient information system and to all other electronic systems that the on-site pharmacist has access to when the pharmacy is open. The remote pharmacist shall receive training in the use of the hospital's electronic systems.

7.7(5) *Nonelectronic patient information.* If a hospital's patient information is not maintained in an electronic data system or if the hospital pharmacy is not able to provide remote electronic access to the patient information system, the hospital pharmacy may petition for a waiver of subrule 7.7(4) pursuant to 657—Chapter 34 and this subrule. In addition to the information required pursuant to 657—Chapter 34, the petition for waiver shall identify the hospital pharmacy's alternative to the electronic sharing of patient information, shall explain in detail how the alternative method will ensure timely provision of patient information necessary for the remote pharmacist to effectively review the patient's drug regimen

and history, and shall detail the processes involved in the alternative proposal including identification of all individuals involved in each of those processes.

7.7(6) *Access to prescriber.* The remote pharmacist shall be able to contact the prescriber to discuss any concerns identified during the pharmacist's review of the patient's information.

7.7(7) *Pharmacist identified.* The record of each patient-specific drug or device order processed pursuant to this rule shall identify, by name or other unique identifier, each pharmacist involved in the preview and verification of the order.

657—7.8(124,126,155A) Drug distribution and control. Policies and procedures governing drug distribution and control shall be developed by the pharmacist in charge 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.* The pharmacist shall institute the control procedures needed to ensure that patients receive the correct drugs at the proper times. Adequate quality assurance procedures shall be developed.

a. All drugs dispensed by the pharmacist for administration to patients shall be in single unit packages if practicable. The need for nurses to manipulate drugs prior to their administration shall be minimized.

b. Pharmacy personnel shall, except as specified in policies and procedures, prepare all sterile products in conformance with 657—Chapter 13.

c. Pharmacy personnel shall compound or prepare drug formulations, strengths, dosage forms, and packages useful in the care of patients.

7.8(2) *Drug formulary.* The pharmacist in charge shall maintain a current formulary of drug products approved for use in the institution and shall be responsible for specifications for those drug products and for selecting their source of supply.

7.8(3) *Medication orders.* Except as provided in subrule 7.8(14), a pharmacist shall receive a copy of the original medication order for review except when the prescriber directly enters the medication order into an electronic medical record system or when the prescriber issues a verbal medication order directly to a registered nurse or pharmacist who then enters the order into an electronic medical record system. If an individual other than the prescriber enters a medication order into an electronic medical record system, the pharmacist shall review and verify the entry against the original order before the drug is dispensed except for emergency use, when the pharmacy is closed, or when the original order is a verbal order from the prescriber to the registered nurse or pharmacist, or as provided in rule 7.7(155A). When the pharmacy is closed, 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 a pharmacist shall verify the entry against the original medication order as soon as practicable. Hospitalwide and pharmacy stand-alone computer systems shall be secure against unauthorized entry. 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(4) *Stop order.* A written policy or other system concerning stop orders shall be established to ensure that medication orders are not inappropriately continued.

7.8(5) *Emergency drug supplies and floor stock.* Supplies of drugs for use in medical emergencies shall be immediately available at each nursing unit or service area as specified in policies and procedures. Authorized stocks shall be periodically reviewed in a multidisciplinary manner. All drug storage areas within the hospital shall be routinely inspected to ensure that no outdated or unusable items are present and that all stock items are properly labeled and stored.

7.8(6) *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(7) *Drugs brought into the institution.* Policies and procedures shall be established governing the use of drugs brought into the institution. Procedures shall address identification of the drug and methods for ensuring the integrity of the product prior to permitting its use by the patient.

7.8(8) *Samples.* The use of drug samples within the institution shall be eliminated to the extent possible. Sample use is prohibited for hospital inpatient use. 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 institution's appropriate patient care committee, subject to oversight by the pharmacy.

7.8(9) *Investigational drugs.* If investigational drugs are used in the institution:

- a. A pharmacist shall be a member of the institutional review board.
- b. The pharmacy shall be responsible, in cooperation with the principal investigator, for providing information about investigational drugs used in the institution and for the distribution and control of those drugs.

7.8(10) *Hazardous drugs and chemicals.* The pharmacist, in cooperation with other hospital staff, shall establish policies and procedures for handling drugs and chemicals that are known occupational hazards. The procedures shall maintain the integrity of the drug or chemical and protect hospital personnel.

7.8(11) *Leave meds.* Labeling of prescription drugs for a patient on leave from the facility for a period in excess of 24 hours shall comply with 657—subrule 6.10(1). The dispensing pharmacy shall be responsible for packaging and labeling leave meds in compliance with this subrule.

7.8(12) *Discharge meds.* Drugs authorized for a patient being discharged from the facility shall be labeled in compliance with 657—subrule 6.10(1) before the patient removes those drugs from the facility premises. The dispensing pharmacy shall be responsible for packaging and labeling discharge meds in compliance with this subrule.

7.8(13) *Own-use outpatient prescriptions.* If the hospital pharmacy dispenses own-use outpatient prescriptions, the pharmacy shall comply with all requirements of 657—Chapter 6 except rule 657—6.1(155A).

7.8(14) *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 polysaccharide vaccines pursuant to physician-approved hospital policy and after the patient has been assessed for contraindications. Administration shall be recorded in the patient's medical record.

657—7.9(124,155A) Drug information. The pharmacy is responsible for providing the institution's staff and patients with accurate, comprehensive information about drugs and their use and shall serve as its center for drug information.

7.9(1) *Staff education.* The pharmacist shall keep the institution's staff well informed about the drugs used in the institution and their various dosage forms and packagings.

7.9(2) *Patient education.* The pharmacist shall help ensure that all patients are given adequate information about the drugs that they receive. This is particularly important for ambulatory, home care, and discharged patients. These patient education activities shall be coordinated with the nursing and medical staffs and patient education department, if any.

657—7.10(124,155A) Ensuring rational drug therapy. An important aspect of pharmaceutical services is that of maximizing rational drug use. The pharmacist, in concert with the medical staff, shall develop policies and procedures for ensuring the quality of drug therapy.

7.10(1) *Patient profile.* Sufficient patient information shall be collected, maintained, and reviewed by the pharmacist to ensure meaningful and effective participation in patient care. This requires that a drug profile be maintained for each patient receiving care at the hospital. A pharmacist-conducted drug history from patients may be useful in this regard.

- a. Appropriate clinical information about patients shall be available and accessible to the pharmacist for use in daily practice.

b. The pharmacist shall review each patient's current drug regimen and directly communicate any suggested changes to the prescriber.

7.10(2) Adverse drug events. The pharmacist, in cooperation with the appropriate patient care committee, shall develop a mechanism for the reporting and review, by the committee or other appropriate medical group, of adverse drug events. The pharmacist shall be informed of all reported adverse drug events occurring in the facility. Adverse drug events include but need not be limited to adverse drug reactions and medication errors.

657—7.11 Reserved.

657—7.12(124,126,155A) Drugs dispensed to patients as a result of an emergency room visit. In those facilities with 24-hour pharmacy services, only a pharmacist or prescribing practitioner may dispense any drugs to an outpatient, including emergency department patients. In those facilities without 24-hour pharmacy services, or in those facilities without outpatient pharmacy services or when the facility's outpatient pharmacy is closed, the following procedures shall be observed in dispensing drugs:

7.12(1) Patients examined in emergency room. Drugs shall be dispensed only to patients who have been examined in the emergency room.

7.12(2) Accountability. Drugs shall be dispensed only in accordance with the system of control and accountability for drugs administered or dispensed from the emergency room.

a. The system shall be developed and supervised by the pharmacist in charge and the facility's emergency department committee, or a similar group or person responsible for policy in that department.

b. The system shall identify drugs of the nature and type to meet the immediate needs of emergency room patients.

c. Controlled substances maintained in the emergency room are kept for use by, or at the direction of, prescribers in the emergency room. In order to receive a controlled substance, a patient must be examined in the emergency room by a prescriber who shall determine the need for the drug. It is not permissible under state and federal requirements for a prescriber to see a patient outside the emergency room setting, or talk to the patient on the telephone, and then proceed to call the emergency room and order the administration of a stocked controlled substance upon the patient's arrival at the emergency room. 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.

d. 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 "c," the emergency room nurse may examine the patient in the emergency room 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. As soon as possible, the prescriber shall examine the patient in the emergency room and determine the patient's further treatment needs.

e. The pharmacist in charge is responsible for maintaining accurate records of dispensing of drugs from the emergency room, and for ensuring the accuracy of prepackaged drugs and the complete and accurate labeling of prepackaged drugs pursuant to subrule 7.12(3).

f. Except as provided in subrule 7.12(6), a practitioner who authorizes dispensing to a patient of a prescription drug from the emergency department drug supply is responsible for the accuracy of the dispensed drug and for the accurate completion of label information pursuant to subrule 7.12(4).

7.12(3) Prepackaging. Except as provided in subrule 7.12(6), drugs dispensed in greater than a 24-hour supply may be dispensed only in prepackaged quantities not to exceed a 72-hour supply or the minimum prepackaged quantity in suitable containers. Prepackaged drugs shall be prepared pursuant to the requirements of 657—22.3(126). Drugs dispensed pursuant to this subrule shall be appropriately labeled as required in subrule 7.12(4), including necessary auxiliary labels.

7.12(4) Labeling. Except as provided in subrule 7.12(6), at the time of delivery of the drug, the practitioner shall appropriately complete the label, such that the dispensing container bears a label with at least the following information:

- a. Name and address of the hospital;
- b. Date dispensed;
- c. Name of prescriber;
- d. Name of patient;
- e. Directions for use;
- f. Name and strength of drug.

7.12(5) Delivery of drug to patient. Except as provided in subrule 7.12(6), the practitioner, or a licensed nurse under the supervision of the practitioner, shall give the appropriately labeled, prepackaged drug to the patient or patient's caregiver. The practitioner, or a licensed nurse under the supervision of the practitioner, 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 provide the patient with a prescription for the additional quantities.

7.12(6) Use of InstyMeds dispensing system. 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 implement the InstyMeds dispensing system in the hospital emergency department only as provided by this subrule.

a. Access to the dispensing machine for the purposes of stocking, inventory, and monitoring shall be limited to pharmacists, pharmacy technicians, and pharmacist-interns.

b. The InstyMeds dispensing system shall be used only in the hospital emergency department for the benefit of patients examined or treated in the emergency department.

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

d. The stock of drugs maintained and dispensed utilizing the InstyMeds dispensing system 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 InstyMeds dispensing system shall be appropriately labeled as provided in 657—subrule 6.10(1), paragraphs “a” through “g.”

f. Prior to authorizing the dispensing of a drug utilizing the InstyMeds dispensing system, the prescriber shall offer the patient the option of being provided a prescription that may be filled at the pharmacy of the patient's choice.

g. When appropriate for an acute condition, the prescriber shall provide to the patient or the patient's agent a prescription for the remainder of drug therapy beyond the supply available utilizing the InstyMeds dispensing system. During consultation with the patient or the patient's agent, the prescriber shall clearly explain the appropriate use of the drug supplied, the need to have a prescription for any additional supply of the drug filled at a pharmacy of the patient's choice, and the need to complete the full course of drug therapy.

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

i. The hospital pharmacist shall review the printout of drugs provided utilizing the InstyMeds dispensing system within 24 hours unless the pharmacy is closed, in which case the printout shall be reviewed during the first day the pharmacy is open following the provision of the drugs. The purpose of the review is to identify any dispensing errors, to determine dosage appropriateness, and to complete a retrospective drug use review of any antimicrobials dispensed in a quantity greater than a 72-hour supply. Any discrepancies found shall be addressed by the pharmacy's continuous quality improvement program.

657—7.13(124,155A) Records. Every inventory or other 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 representative for at least two years from the date of such inventory or record unless a longer retention period is specified for the particular inventory or record.

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

- a. Patient name and identification number;
- b. Drug name, strength, and dosage form;
- c. Directions for use;
- d. Date ordered;
- e. Practitioner's signature or electronic signature or that of the practitioner'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.

These rules are intended to implement Iowa Code sections 124.301, 124.303, 124.306, 126.10, 126.11, 155A.6, 155A.13, 155A.27, 155A.28, 155A.31, and 155A.33 through 155A.36.

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[◇] Two or more ARCs