

PHARMACY BOARD [657]

Adopted and Filed

The Board of Pharmacy hereby amends Chapter 5, “Pharmacy Support Persons,” Chapter 7, “Hospital Pharmacy Practice,” and Chapter 8, “Universal Practice Standards,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in 124.301 and 147.76.

State or Federal Law Implemented

This rule making implements, in whole or in part, 124.301, 124.303, 124.306, 124.308, 126.10, 126.11, 155A.6A to 155A.7, 155A.13, 155A.15, 155A.27, 155A.28, 155A.31 to 155A.36, 155A.38, 155A.41, 155A.43, and 155A.44.

Purpose and Summary

Pursuant to Iowa Code section 17A.7(2), the Board has conducted an overall review of Chapters 5 and 7 of its administrative rules. The amendments update requirements for references to be consistent with recent Board action for other practice settings, provide clarification where needed, reorganize where appropriate, remove the requirements that the hospital’s approved drug formulary be included in the pharmacy’s policies and procedures, add documentation requirements related to the pharmacy’s accountability of stock supplies of controlled substances previously required in Chapter 10, update language relating to outpatient automated dispensing systems to use a general term rather than a specific industry brand product, clarify that outpatient automated dispensing systems do not qualify for a unique pharmacy license, and update storage requirements for records to be consistent with recent Board action for other practice settings.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on September 26, 2018, as **ARC 4029C**.

The Board received comments from the National Association of Chain Drug Stores (NACDS) and the Iowa Pharmacy Association (IPA). NACDS, while overall supportive and appreciative of the “common sense updates,” requested the Board consider extending the deadline by which a pharmacy must retrieve records from an offsite location from 48 hours to 72 hours. Since the Board has rules relating to the production of records within 48 hours from a Board request in four other administrative rules, the Board determined that the suggestion should be considered in relation to all applicable rules at a later time. The comments from IPA included two suggested changes. It was suggested to remove the clarifier “long-acting anti-psychotic” as it relates to the use of samples in the hospital setting. The Board declined to make this change. The second suggestion was to modify slightly the language relating to the use of medications stocked into an outpatient point-of-care automated dispensing system, which the Board agreed with modification. The only change from the Notice is found in subrule 7.12(4) with “prepackaged, pharmacist-verified medications” being changed to “prepackaged medications verified by authorized pharmacy personnel.”

Adoption of Rule Making

This rule making was adopted by the Board on January 9, 2018.

Fiscal Impact

This rule making has no fiscal impact to the state of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 657-Chapter 34.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on _____, 2019.

The following rule-making action is adopted:

ITEM 1. Amend rule 657—5.22(155A) as follows:

657—5.22(155A) Delegation of nontechnical functions. A pharmacist may delegate nontechnical functions to an appropriately trained and registered pharmacy support person, but only if the pharmacist is present to supervise the pharmacy support person when delegated functions are performed, except as provided in ~~657—subrule 6.7(2)~~ rule 657—6.7(124,155A) or ~~657—subrule 7.6(2)~~ 657—7.6(155A), as appropriate.

ITEM 2. Amend rule 657—7.3(155A) as follows:

657—7.3(155A) Reference library. ~~References may be printed or computer accessed. A pharmacy shall maintain a reference library shall be maintained which includes, at a minimum, one current reference from each of the following categories, including access to current periodic updates 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 ~~general~~ 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 as may be necessary for the pharmacist to adequately meet the needs of the patients served relating to specific patient populations served, such as pediatrics or geriatrics, or disease states treated, such as oncology or infectious disease. For example, the treatment of pediatric patients and oncology patients would require additional references unique to those specialties.~~

ITEM 3. Renumber rule ~~657—7.6(124,155A)~~ as ~~657—7.5(124,155A)~~.

ITEM 4. Amend renumbered rule ~~657—7.5(124,155A)~~ as follows:

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) Pharmacist responsibility *Pharmacy department security.* Each pharmacist, while on duty, shall be responsible for Policies and procedures shall identify measures to ensure the security of the pharmacy area 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 as provided in 657—Chapter 21, including when the pharmacist is absent from the pharmacy department or absent from the facility pursuant to rule 657—7.6(155A). Policies and procedures shall identify the minimum amount of time that a pharmacist is available at the hospital pharmacy.~~

~~7.5(2) Access when pharmacist absent.~~ When the pharmacist is absent from the facility, the pharmacy is closed and shall be secured from public access. 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 or pharmacy support persons who may be present in the pharmacy to perform technical or nontechnical functions, respectively, 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 or a pharmacy support person to perform designated functions when the pharmacy is closed, only a certified pharmacy technician may assist another authorized, licensed health care professional to locate a drug or device pursuant to an emergent need. The pharmacy technician or the pharmacy support person 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 or the pharmacy support person to verify that the appropriate drug, chemical, or device has been obtained from the pharmacy.~~

~~c. A pharmacy technician or a pharmacy support person 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 pharmacy technician or pharmacy support person 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 or~~

pharmacy support person 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 or a pharmacy support person 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.~~

~~7.5(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.~~

~~7.5(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.~~

~~7.5(5) 7.5(2) Drugs or devices in patient care areas Security outside the pharmacy department. 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. 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(6) 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. Federal regulations regarding disposal of controlled substances can be found at http://deادiversion.usdoj.gov/drug_disposal/.~~

~~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.~~

ITEM 5. Adopt the following **new** rule 657—7.6(155A):

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 onsite 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 tech-check-tech 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.

ITEM 6. Amend rule 657—7.7(155A) as follows:

657—7.7(155A) Verification by remote pharmacist. A hospital pharmacy may contract with ~~another~~ an Iowa-licensed pharmacy or pharmacist for remote pharmacist ~~preview and verification of patient specific drugs or devices ordered for a patient. Contracted services may include pharmacist order entry pursuant to subrule 7.8(3) 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 ~~cognitive and 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 ~~cognitive and clinical~~ patient care activities, and those records shall be available for inspection by the board or an its authorized agent of the board.

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~~ pharmacist services identified in this chapter in compliance with this rule. 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 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) ~~Electronic access to patient information~~ Remote access requirements. ~~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. 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.

~~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. The record of each patient-specific drug or device visually verified pursuant to this rule shall identify, by name or other unique identifier, each pharmacist involved in the visual verification of the product.

ITEM 7. Amend rule 657—7.8(124,126,155A) as follows:

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. ~~Pharmacy personnel shall, except as specified in policies and procedures, prepare all~~ All sterile and nonsterile compounded products shall be prepared in conformance with 657—Chapter 20.

~~e. Pharmacy personnel shall compound or prepare drug formulations, strengths, dosage~~

forms, and packages useful in the care of patients.

~~7.8(2) Drug formulary.~~ Established policies and procedures shall include a current formulary of drug products approved for use in the institution and shall include specifications for those drug products.

~~7.8(3) 7.8(2) Medication orders.~~ Except as provided in subrule 7.8(14) or this subrule, a pharmacist shall receive a copy of an original written 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. 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, ~~the~~ 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. System security.* Hospitalwide and pharmacy stand alone computer systems shall be secure against unauthorized entry. System login or access credentials issued to an authorized system user shall not be shared or disclosed to any other individual.~~

~~*e. 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(4) 7.8(3) 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) 7.8(4) Emergency drug supplies and floor stock.~~ Supplies Pursuant to policies and procedures, 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 facility shall be routinely inspected to ensure that no outdated or unusable items are ~~present~~ available for administration and that all stock items are properly labeled and stored.

~~7.8(6) 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(7) 7.8(6) Drugs brought into the institution facility.~~ Established policies and procedures shall determine those circumstances when patient-owned drugs brought into the ~~institution~~ facility may be administered to a hospital the patient and shall identify procedures governing the use and security of drugs brought into the ~~institution~~ facility. Procedures shall address

identification of the drug and methods for ensuring the integrity of the product prior to permitting its use ~~by the patient~~. The use of patient-owned drugs shall be minimized to the greatest extent possible.

~~7.8(8)~~ 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. ~~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.~~ 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(9)~~ 7.8(8) *Investigational drugs*. If investigational drugs are used in the ~~institution~~ 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 ~~institution~~ facility and for the distribution and control of those drugs.

~~7.8(10)~~ 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 ~~hospital~~ facility personnel.

~~7.8(11)~~ 7.8(10) *Leave and discharge meds*. Labeling of ~~prescription drugs~~ 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). ~~The dispensing pharmacist 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 pharmacist shall be responsible for packaging and labeling discharge meds in compliance with this subrule.~~

~~7.8(13)~~ 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(14)~~ 7.8(12) *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 ~~hospital~~ 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.

ITEM 8. Amend rule 657—7.9(124,155A) as follows:

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

ITEM 9. Amend rule 657—7.10(124,155A) as follows:

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. 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. 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.~~

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

~~b. The pharmacist shall Upon review each of a patient's current drug regimen and clinical profile, the pharmacist shall directly communicate any suggested changes to the ~~prescriber~~ patient's health care team.~~

7.10(2) Adverse drug events. Established policies and procedures shall include a mechanism for the reporting and review, ~~by the committee or other appropriate medical group,~~ 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 ~~need~~ are not be limited to adverse drug reactions and medication errors.

ITEM 10. Amend rule 657—7.11(124,126,155A) as follows:

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 ~~drug order~~ shall be ~~provided to the patient~~ 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 ~~an individual~~ a patient who is examined and evaluated in the emergency department.

“Outpatient” means ~~an individual~~ a patient who was examined and evaluated by a prescriber who determined the ~~individual’s~~ patient’s need for the administration of a drug or device, ~~which individual~~ 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 ~~a written~~ an order ~~from~~ issued by a prescriber ~~or an oral or electronic order from a prescriber or the prescriber’s authorized agent~~ 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 ~~receive~~ 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 outside other than the outpatient setting, the prescriber shall ~~provide the patient with~~ issue a ~~written~~ prescription or order ~~to be presented at~~ 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 ~~written~~ 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 ~~written~~ 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.

ITEM 11. Amend rule 657—7.12(124,126,155A) as follows:

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 ~~an individual~~ a patient who is examined and evaluated in the emergency department.

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 ~~immediate~~ emergency needs of ~~emergency department~~ 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. to c. No change.

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, ~~with a valid written prescription or order~~ for the administration of the 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. ~~In those facilities with 24-hour pharmacy services, only~~ Only a pharmacist or prescriber may dispense any drugs to an emergency department patient. ~~In those facilities located in an area of the state where 24-hour outpatient or 24-hour on-call pharmacy services are not available within 15 miles of the hospital, and which facilities are without 24-hour outpatient pharmacy services, pursuant to the provisions of this rule shall apply.~~

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

(1) ~~Prepackaging.~~ Except as provided in subrule 7.12(4), drugs dispensed to an emergency department patient ~~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, except that ~~a seven-day~~ an authorized supply of ~~doxycycline~~ a drug provided through the department of public health ~~pursuant to the crime-victim compensation program of the Iowa department of justice~~ 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) ~~Labeling.~~ 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) ~~Labeling.~~ Except as provided in subrule 7.12(4), at the time of delivery of the drug the prescriber shall ~~appropriately complete the label such~~ 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;
5. Directions for use;
6. Name, quantity, and strength of drug.

(2) ~~Delivery of drug to patient.~~ 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, ~~prepackaged~~ 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 ~~provide the patient with~~ issue a prescription for the additional quantities to be filled at a pharmacy of the patient's choice.

7.12(4) *Use of ~~InstyMeds~~ 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 ~~implement the InstyMeds~~ utilize an outpatient point-of-care automated dispensing system (OPCADS) in the ~~hospital~~ 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 ~~dispensing machine~~ OPCADS for the purposes of stocking, inventory, and monitoring shall be limited to pharmacists, pharmacy technicians, and pharmacist-interns.

b. The ~~InstyMeds dispensing system~~ OPCADS shall be used only in the ~~hospital~~ 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 ~~dispensing machine~~ OPCADS shall be located in a secure and professionally appropriate environment.

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

f. Prior to authorizing the dispensing of a drug utilizing the ~~InstyMeds dispensing system~~

OPCADS, the prescriber shall offer to issue the patient the option of being provided a prescription that may be filled at the a pharmacy of the patient's choice.

~~g. When appropriate for an acute condition, the prescriber shall provide to the patient or the patient's caregiver 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 caregiver, the prescriber or licensed nurse under the supervision of 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. 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 hospital emergency department, implement policies and procedures to ensure that a patient utilizing the InstyMeds dispensing system OPCADS 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.~~

ITEM 12. Amend rule 657—7.13(124,155A) as follows:

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~~ authorized agent 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~~ 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. ~~Practitioner's~~ Prescriber's signature or electronic signature or that of the ~~practitioner's~~ prescriber's authorized agent.

7.13(2) and 7.13(3) No change.

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 48 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 48 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

ITEM 13. Amend ~~657~~—**Chapter 7**, implementation sentence, as follows:

These rules are intended to implement Iowa Code sections 124.301, 124.303, 124.306, 124.308, 126.10, 126.11, ~~155A.6~~, 155A.6A, 155A.6B, 155A.7, 155A.13, 155A.15, 155A.27, 155A.28, 155A.31, ~~and 155A.33~~ through 155A.36, 155A.38, 155A.41, 155A.43, and 155A.44.

ITEM 14. Amend subrule 8.5(3) as follows:

8.5(3) *Secure barrier.* A pharmacy department shall be closed and secured in the absence of the pharmacist except as provided in rule ~~657—6.7(124,155A)~~ or ~~657—7.6(124,155A)~~ 657—7.5(124,155A). To ensure that secure closure, the pharmacy department shall be surrounded by a physical barrier capable of being securely locked to prevent entry when the department is closed. A secure barrier may be constructed of other than a solid material with a continuous surface if the openings in the material are not large enough to permit removal of items from the pharmacy department by any means. Any material used in the construction of the barrier shall be of sufficient strength and thickness that it cannot be readily or easily removed, penetrated, or bent.