CHAPTER 9
AUTOMATED MEDICATION DISTRIBUTION SYSTEMS AND TELEPHARMACY SERVICES

657—9.1(155A) Purpose and scope. The purposes of this chapter are to provide standards for the utilization of automated medication distribution systems in the practice of pharmacy and to provide standards for the provision of telepharmacy services to patients in areas of Iowa without local pharmacy services. These rules provide for pharmacy services at a remote dispensing site utilizing an automated pharmacy system that is linked to a managing pharmacy. Both the remote dispensing site and the managing pharmacy shall be located within Iowa and appropriately licensed by the board.

657—9.2(147,155A) Definitions. For the purposes of this chapter, the following definitions shall apply:

"Automated medication distribution system" or *"AMDS"* includes, but is not limited to, an automated device or series of devices operated by an electronic interface with one or more computers that is used to prepare, package, or dispense specified dosage units of drugs for administration or dispensing to a patient or the ultimate user. "AMDS" includes a device that prepares and packages a drug for unit dose dispensing, that prepares and packages a drug into outpatient prescription vials, and that dispenses prepackaged drugs.

"Automated pharmacy system" means a system that utilizes an automated medication distribution system to monitor and control the dispensing of prescription drugs and that provides for related drug use review and patient counseling via an electronic method that includes the use of linked computer, audio, and video communication technologies between a managing pharmacy and a remote dispensing site.

"Board" means the board of pharmacy.

"Centralized unit dose AMDS" means an AMDS located within the pharmacy department where automated technology is utilized in the dispensing of patient-specific unit dose drugs.

"Component" means any single physical or electronic storage or access device that, in combination with other devices, makes up the AMDS.

"DEA" means the Drug Enforcement Administration of the U.S. Department of Justice.

"Decentralized unit dose AMDS" means an AMDS where automated technology is utilized in the dispensing of unit dose drugs for administration to patients in an institutional setting and drug-dispensing components are maintained within the institution but outside the pharmacy department.

"Drug access" means the physical entry into any component of the AMDS for the purpose of stocking or removing drugs.

"Drug bin" means a compartment in an AMDS component that is designed to contain one specific drug.

"Emergency drugs" means those drugs critical for patient care and approved by the institution's pharmacy and therapeutics committee or equivalent committee. Drugs critical for patient care include drugs requiring administration within minutes or within less time than the pharmacy can be practically expected to respond, such as the administration of naloxone for treatment of an opioid overdose.

"Floor-stock drugs" means those drugs consisting of emergency drugs and controlled substances which are routinely maintained on patient care units and accessible by nursing staff for patient administration.

"Information access" means the entry into a record-keeping component of the AMDS, by electronic or other means, for the purpose of adding, updating, or retrieving any patient record or drug record or data.

"Managing pharmacy" means a licensed community pharmacy providing telepharmacy services at one or more licensed remote dispensing sites.

"Outpatient AMDS" means an AMDS where automated technology is utilized in the dispensing of prescriptions for ambulatory patients and includes an AMDS located at a remote dispensing site.

"Qualified certified pharmacy technician" or *"technician"* means a pharmacy technician registered in good standing with the board who has obtained and maintains current certification by a national technician certification authority approved by the board pursuant to 657—Chapter 3.

"Remote dispensing site" or *"remote site"* means a licensed pharmacy staffed by one or more qualified certified pharmacy technicians at which telepharmacy services are provided through a licensed managing pharmacy.

"Telepharmacy" means the provision of pharmaceutical care services, including the storage and dispensing of prescription drugs, drug regimen review, and patient counseling, at a remote dispensing site using an automated pharmacy system.

657—9.3(147,155A) Pharmacist in charge responsibilities.

9.3(1) *AMDS.* The pharmacist in charge of any pharmacy utilizing an AMDS shall be responsible for the following in addition to other responsibilities assigned under federal and state laws and regulations:

a. Implementing an ongoing quality assurance program which purpose is to monitor and improve performance of each AMDS as provided in rule 9.10(147,155A).

b. Establishing and ensuring compliance with all policies and procedures relating to the AMDS.

c. Assigning, discontinuing, or changing drug and information access to the AMDS.

d. Ensuring that drug access, including access to controlled substances, is in compliance with state and federal regulations.

e. Ensuring that each AMDS component is filled or stocked accurately and in accordance with established, written policies and procedures.

f. Ensuring that each AMDS component is in good working order and performs its designated tasks, including ensuring the correct strength, dosage form, and quantity of the prescribed drug.

g. Ensuring that the AMDS has adequate security safeguards regarding drug access and information access.

h. Ensuring that confidentiality of patient-specific information is maintained.

i. Ensuring that all personnel utilizing or accessing the AMDS or any component of the AMDS have been appropriately trained.

j. Ensuring that the board is provided with written notice at least 30 days prior to an installation, removal, or upgrade that significantly changes the operation of an AMDS. The notice shall include:

(1) The name, address, and license number of the pharmacy;

(2) The location of the automated equipment;

(3) Identification of the pharmacist in charge;

(4) The name, manufacturer, and model of the system;

(5) A description of the change or upgrade, if applicable, and a description of the intended use of the equipment; and

(6) If a new or significantly changed AMDS will be installed or upgraded, a copy of the quality assurance plan.

9.3(2) *Telepharmacy.* The pharmacist in charge of the managing pharmacy shall also serve as the pharmacist in charge of the remote dispensing site. In addition to other responsibilities assigned under federal and state laws and regulations, including the responsibilities identified in rule 657—6.2(155A), the pharmacist in charge shall be responsible for, at a minimum, the following:

a. Submitting for board approval the operational plan for the telepharmacy service, including identification of the managing pharmacy; identification of the remote dispensing site; the names and titles of key personnel at both locations; the quality assurance and improvement plan; policies and procedures as provided in rule 9.11(147,155A); identification of the AMDS as provided in subrule 9.3(1), paragraph *"j"*; justification of the need for the telepharmacy service as provided in subrule 9.5(2); and a copy of the proposed contract between the managing pharmacy and the remote dispensing site.

b. Maintaining all licenses and registrations required of the managing pharmacy and of the remote dispensing site.

c. Ensuring that the practice of telepharmacy performed at a remote dispensing site, including the utilization of an automated pharmacy system and the supervision of one or more qualified certified pharmacy technicians, complies with these rules and other applicable rules of the board.

d. Ensuring that the managing pharmacy and the remote dispensing site have entered into a written contract as provided by subrule 9.5(6).

e. Ensuring that the automated pharmacy system is in good working order and that the AMDS accurately dispenses the correct strength, dosage form, and quantity of the prescribed drug and accurately prints the prescription label, while maintaining appropriate record-keeping and security safeguards.

f. Ensuring that all pharmacists, pharmacist-interns, and pharmacy technicians authorized to engage in telepharmacy services at the managing pharmacy or the remote site maintain current licensure or registration with the board and are trained in the operation of the automated pharmacy system and familiar with policies and procedures relating to the telepharmacy practice.

g. Ensuring that a pharmacist completes and documents monthly inspections of each remote site pursuant to subrule 9.5(8).

657—9.4 Reserved.

657—9.5(124,155A) General requirements for telepharmacy. The pharmacist in charge of the managing pharmacy shall ensure that the managing pharmacy and the remote site have obtained all necessary licenses, registrations, and authorizations prior to engaging in the practice of telepharmacy at the remote dispensing site. Regardless of the fact that both the managing pharmacy and the remote site are required to be licensed, the remote site is considered an extension of the managing pharmacy.

9.5(1) *License requirements.*

a. Managing pharmacy. A managing pharmacy shall maintain a license issued by the board pursuant to 657—8.35(155A). The license shall be a general pharmacy license. A managing pharmacy engaged in the dispensing of controlled substances shall maintain registrations with the DEA and the board.

b. Remote dispensing site. A remote site shall maintain a license issued by the board pursuant to 657—8.35(155A). The application for initial licensure shall include the information identified in subrules 9.5(2) and 9.5(6). The license shall be a limited use pharmacy license. If controlled substances are maintained at or dispensed from the remote site, the remote site shall maintain registrations with the DEA and the board that authorize the stocking and dispensing of controlled substances from the remote site.

9.5(2) *Need for remote dispensing site.* Prior to engaging in the practice of telepharmacy with a remote dispensing site, the managing pharmacy shall demonstrate to the board that there is limited access to pharmacy services in the community where the remote site is located.

a. Information justifying the need for the remote dispensing site shall be submitted to the board with the initial application for licensure of the remote site as a limited use pharmacy.

b. The board shall consider the availability of pharmacists in the community, whether the request is for availability of patient care in a critical access area or is solely for the benefit of the managing pharmacy, whether any benefit to the managing pharmacy will balance the benefit to the patients of the remote dispensing site, the population of the community to be served by the remote site, and the need for the service.

c. The board shall not approve a remote dispensing site if a general pharmacy that dispenses prescription drug orders to outpatients is located within the same community as the proposed remote site or is located within 15 miles of the proposed remote dispensing site.

9.5(3) *Reference library.* A managing pharmacy shall comply with the requirements for a reference library found at 657—6.3(155A); a remote site shall be exempt from complying with the requirements for a reference library.

9.5(4) *Patient notification.* A remote site shall display a sign, easily visible to the public, that informs patients that the location is a remote dispensing site providing telepharmacy services supervised by a pharmacist located in another pharmacy, that identifies the city where the managing pharmacy is located, and that informs patients that a pharmacist is required to speak with the patient over an audiovisual link each time a prescription drug is delivered to the patient at the remote site.

9.5(5) *Environment and equipment.* A managing pharmacy and a remote site shall comply with the requirements for environment and equipment found at 657—8.5(155A) except that a remote site that

does not dispense drugs requiring refrigeration shall be exempt from complying with the requirements of 657—subrule 8.5(1).

9.5(6) *Written contract.* A managing pharmacy and a remote dispensing site, unless jointly owned, shall enter into a written contract that outlines the services to be provided and the responsibilities and accountability of each party in fulfilling the terms of the contract in compliance with federal and state laws and regulations.

a. A copy of the contract shall be submitted to the board for approval with the initial application for licensure of the remote site as a limited use pharmacy and at any time there is a substantial change in any of the terms of the contract.

b. The contract shall be maintained by the managing pharmacy and shall be available for inspection or copying by the board or an agent of the board for a minimum of two years following expiration or other termination of the contract.

9.5(7) *Changes relating to remote dispensing site.* Pursuant to the requirements of 657—8.35(155A), a managing pharmacy shall notify the board of a change of name, change of location, change of ownership, change of pharmacist in charge, discontinuance of service, or closure of a remote dispensing site operated by the managing pharmacy. A managing pharmacy shall also notify the board of any change of qualified certified pharmacy technician staffing at a remote dispensing site.

9.5(8) *Monthly inspection.* A pharmacist shall complete and document the monthly inspection of a remote dispensing site. Inspection criteria shall be identified in the policies and procedures for the remote site, and inspection reports shall be maintained and available to the board or an agent of the board for review and copying for a minimum of 12 months from the date of the monthly inspection or until the next board inspection, whichever period is longer.

657—9.6(155A) Duties of pharmacist in telepharmacy practice. The following activities shall be performed only by a pharmacist at the managing pharmacy or at the remote dispensing site. These activities may not be delegated to a pharmacy technician at a remote site.

1. Receiving an oral prescription drug order from a prescriber or the prescriber's agent for dispensing to a patient at the remote site.
2. Interpreting a prescription drug order.
3. Verifying the accuracy of prescription data entry.
4. Interpreting the patient's drug record and conducting a drug use review.
5. Authorizing the AMDS to dispense a prescription drug and print a prescription label at the remote site.
6. Performing the final verification of a dispensed prescription as specified in subrule 9.18(7) to ensure that the prescription drug order has been accurately dispensed as prescribed.
7. Counseling the patient or the patient's caregiver as specified in subrule 9.18(8).
8. Completing and documenting the monthly inspection of the remote site pursuant to subrule 9.5(8).

657—9.7 to **9.9** Reserved.

657—9.10(147,155A) Quality assurance and performance improvement. The goal of any AMDS is the accurate dispensing of drugs. In all dispensing activities, the pharmacy shall strive for 100 percent accuracy. Quality assurance data shall be utilized to monitor and improve systems.

9.10(1) *AMDS.* Pharmacies utilizing an AMDS shall develop a written quality assurance and monitoring plan prior to implementation of the AMDS. The quality assurance plan shall target the preparation, delivery, and verification of AMDS unit contents during fill and refill processes and shall include, but not be limited to, the following:

a. Requiring continuous monitoring of the system.
b. Establishing mechanisms and procedures to test the accuracy of the system.
c. Establishing a protocol for measuring the effectiveness of the system.
d. Requiring the pharmacy to report to the board each recurring error of the system.

9.10(2) *Telepharmacy.* In addition to the requirements of subrule 9.10(1), a managing pharmacy that provides telepharmacy services at a remote dispensing site shall operate according to a written program for quality assurance that includes, but is not limited to, the following:

a. Requiring continuous supervision of the remote dispensing site at all times when the remote site is open to provide telepharmacy services.

b. Requiring a pharmacist at the managing pharmacy to be accessible to respond to inquiries or requests pertaining to drugs that are dispensed by utilizing the automated pharmacy system located at the remote dispensing site.

c. Establishing procedures to test the operation of all aspects of the automated pharmacy system, including all electronic audio and video communication components, at a minimum of every six months and whenever any upgrade or change is made to the system, and to document the testing of each system.

d. Establishing a written plan for recovery from a failure of the automated pharmacy system or any component of the system pursuant to subrule 9.10(3).

9.10(3) *Recovery from failure of the automated pharmacy system.* The written plan for recovery from an event that interrupts the ability of a pharmacist to electronically supervise the automated pharmacy system and the dispensing of drugs at the remote dispensing site shall include, at a minimum, the following:

a. A statement that drugs shall not be dispensed at the remote dispensing site if a pharmacist is not available or able to electronically supervise such dispensing, including the utilization of audio and video communication, or if a pharmacist is not on site at the remote dispensing site to personally dispense the drugs.

b. Procedures for response when the automated pharmacy system is experiencing downtime.

c. Procedures for the maintenance and testing of the written plan for recovery.

d. Procedures for notifying the board and other appropriate agencies or organizations of a disaster affecting the ability of the pharmacy to provide services for an extended period of time, including the date on which the pharmacy expects to recommence services.

9.10(4) *Records.* All records and documentation of quality assurance and monitoring, performance improvement projects, and recovery from system failure shall be maintained by the managing pharmacy and be available for inspection and copying by the board or its representative for a minimum of two years from the date of the record.

657—9.11(147,155A) Policies and procedures. All policies and procedures shall be in writing and shall be maintained in the pharmacy responsible for the AMDS or, if a telepharmacy practice, shall be maintained at both the managing pharmacy and the remote site. All policies and procedures shall be reviewed at least annually and revised as necessary, and the review shall be documented. Additions, deletions, amendments, and other changes to policies and procedures shall be signed or initialed by the pharmacist in charge, shall include the date on which the change was approved, and shall be maintained for a minimum of two years following the date of the change. The policy and procedure manual and retained changes shall be available for inspection and copying by the board or an agent of the board.

9.11(1) *AMDS.* All pharmacies utilizing AMDS shall develop, implement, and adhere to policies and procedures that address, at a minimum, the following:

a. Type of equipment, system components, and location of each system component including:

(1) Name and address of the pharmacy, including identification of the specific location within an institution but outside the pharmacy where any component of the AMDS is being used;

(2) Name and address of any remote dispensing site where a component of the AMDS is being used; and

(3) Manufacturer's name and model of each system component.

b. Drug access and information access procedures.

c. Security and confidentiality of records in compliance with 657—8.16(124,155A) and 657—21.2(124,155A).

d. Description of how each component is being utilized, including processes for dispensing and distributing drugs.

e. Staff education and training.

f. Review, including prospective drug use review, of medication orders and prescriptions in accordance with federal and state laws and regulations.

g. Patient counseling on outpatient prescriptions.

h. Quality assurance and quality improvement.

i. Downtime or system failure procedures.

j. Periodic system maintenance and preventive maintenance.

k. Drug security and control including:

(1) Drug loading, storage, and records.

(2) Drugs removed from system components but not used.

(3) Inventory.

(4) Cross contamination.

(5) Lot number control.

(6) Wasted or discarded drugs.

(7) Controlled substances.

9.11(2) *Telepharmacy.* In addition to other requirements for policies and procedures relating to pharmacy practices and the requirements of subrule 9.11(1) relating to policies and procedures for utilization of the AMDS, pharmacies engaging in telepharmacy shall develop, implement, and adhere to policies and procedures that address, at a minimum, the following:

a. Security, including identification by name of the personnel designated by the pharmacist in charge to have access to drug storage and dispensing areas at the remote dispensing site and to receive drugs delivered to the remote dispensing site.

b. Operation of the automated pharmacy system, including identification by name of the personnel designated by the pharmacist in charge to operate the system from the remote site or from the managing pharmacy, and identification by name of the individuals responsible for daily and periodic testing of the automated pharmacy system.

c. Identification of duties that may be performed only by a pharmacist.

d. Sanitation.

e. Storage of drugs and devices at the remote site.

f. Dispensing and delivery of drugs and devices from the remote site.

g. Supervision of remote site personnel.

h. Procurement, receipt, and delivery of drugs and devices to the remote site and into AMDS components.

i. Records.

j. Monthly pharmacist inspection of the remote dispensing site, including documentation of inspection.

k. The frequency of review of the policy and procedure manual and required documentation of that periodic review.

657—9.12(147,155A) System, site, and process requirements. An AMDS may be utilized on site by licensed pharmacies or in board-approved remote dispensing sites engaged in the practice of telepharmacy. Each AMDS shall comply with the following minimum requirements:

9.12(1) *System access.*

a. The AMDS shall automatically and electronically record drug access.

b. Drug access and information access records shall include, at a minimum, the date the AMDS was accessed, the identity of the individual who accessed the system, the type of transaction completed, and the identity of the accessed component.

c. Information access for the purpose of retrieving or reviewing any patient or drug record or data, when the access does not permit change or addition to the record or data, shall be exempt from the access record requirements of paragraph *"b"* of this subrule.

d. The AMDS shall include the ability to assign, discontinue, and change an individual's access to drugs and information in the AMDS.

e. A licensed pharmacist or appropriately trained pharmacy technician under the oversight of a licensed pharmacist shall fill and stock drugs into AMDS components.

f. A record of drugs filled or stocked into an AMDS component shall be maintained and shall include identification of the person filling or stocking the system and, if applicable, the person checking for accuracy.

9.12(2) *Dispensing and distributing.*

a. All containers of drugs stored in each AMDS shall be packaged and labeled in compliance with federal and state laws and regulations.

b. All aspects of handling controlled substances dispensed utilizing an AMDS shall be in compliance with the requirements of all state and federal laws and regulations.

c. Each centralized or decentralized AMDS shall provide a mechanism for securing and accounting for drugs removed from and subsequently returned to the system. Drugs removed from a system component but not administered to a patient shall be returned to the pharmacy or maintained in a manner that would prevent access to the returned drugs except for the purpose of returning the drugs to the pharmacy. The provisions of this paragraph regarding preventing access to returned drugs except for return to the pharmacy shall not apply, for a decentralized unit dose AMDS, to items that are too large or bulky to be inserted into the system's return bin, to items requiring refrigeration, or to limited critical care items whose inaccessibility would compromise patient care. The provisions of this paragraph shall not apply to an AMDS utilized in telepharmacy.

d. Each centralized or decentralized AMDS shall provide a mechanism for securing and accounting for wasted or discarded drugs in compliance with federal and state laws and regulations. The provisions of this paragraph shall not apply to an AMDS utilized in telepharmacy.

e. An AMDS utilized in telepharmacy shall not permit the wasting or discarding of drugs. The automated pharmacy system shall provide that any drugs removed from the AMDS component but not delivered to the patient shall be maintained in a manner that prevents access to the drugs except for the purpose of returning the drugs to the managing pharmacy. The technician at a remote dispensing site shall not accept drugs returned by a patient or patient's agent.

9.12(3) *Security and confidentiality.* An AMDS shall include system safeguards designed to prevent and detect unauthorized drug access, including access to controlled substances. System safeguards shall also be designed to prevent and detect unauthorized access to information for the purpose of modification or manipulation of patient records and prescription drug orders.

a. An AMDS shall be capable of generating reports of all drug access activity. Reports shall include, at a minimum for each drug access record, the following:

(1) Identification of the person accessing the drug or drug bin.
(2) The date and, preferably, the time.
(3) Identification of the specific drug or drug bin.
(4) Whether the drug access involved stocking, dispensing, wasting, or returning the drug.
(5) The quantity of the drug.
(6) The accessed component.

b. An AMDS shall maintain confidential patient records and information in compliance with rules 657—8.16(124,155A) and 657—21.2(124,155A).

657—9.13(147,155A) Records. All records required pursuant to these rules, unless otherwise specifically identifying a different retention period, shall be available to the board or its authorized agents for two years following the recorded activity.

657—9.14 Reserved.

657—9.15(147,155A) Decentralized unit dose AMDS. Components of a decentralized unit dose AMDS utilized for the storage and dispensing of drugs in an institutional setting may be restocked with drugs by an appropriately trained pharmacy technician following pharmacist verification in the pharmacy of each dose of the drug to be restocked. The provisions of either subrule 9.15(1) or 9.15(2)

shall also apply based on whether or not bar coding or other technology-based verification is utilized to check the accuracy of drug dose placement in the AMDS component.

9.15(1) *No technology-based verification is available or used.* When bar coding or other technology-based verification is not utilized to check the accuracy of drug doses stocked in a dispensing component, a pharmacist shall check each drug dose prior to releasing the drugs from the pharmacy.

a. Following restocking of drug doses into the AMDS component, a pharmacist or a nurse shall verify that 100 percent of all drug doses are accurately placed in each drug bin of each dispensing component.

b. Policies, procedures, and safeguards shall be developed and implemented that control, while ensuring availability and access to needed drugs, utilization of drugs added to the dispensing component prior to pharmacist or nurse verification of the addition. Policies and procedures shall also provide for documentation identifying the individual who provides verification of drugs stocked in dispensing components.

9.15(2) *Bar coding or technology-based verification is available and used.* When bar coding or other technology-based verification is utilized to check the accuracy of drug doses stocked in a dispensing component and a nonpharmacist fills the component, a pharmacist shall check each drug dose prior to releasing the drugs from the pharmacy. The quality assurance plan shall provide for random verification by a pharmacist utilizing one of the methods described in paragraphs *"a"* and *"b"* below. A pharmacy may petition the board pursuant to 657—Chapter 34 for a variance for an alternate pharmacist verification process.

a. One day each month, all drug doses or bins contained in 5 percent of the components utilized within the system shall be verified by a pharmacist.

b. One day each month, 5 percent of the drug doses or bins contained in each component utilized within the system shall be verified by a pharmacist. If, however, the system includes fewer than five components, a pharmacist shall, one day each month, verify all drug doses or bins contained in one component utilized within the system.

9.15(3) *Errors identified.* All identified errors shall be logged as provided by the quality assurance and monitoring plan developed pursuant to rule 9.10(147,155A) and shall be categorized as follows:

a. Incorrect drug;

b. Incorrect dose;

c. Incorrect dosage form;

d. Other errors. All errors categorized as "other errors" shall include additional notation identifying the error.

657—9.16(147,155A) Centralized unit dose AMDS. The quality assurance plan shall provide for pharmacist verification of all drug doses dispensed for a minimum of 60 days following implementation of the AMDS.

9.16(1) *Errors logged.* All identified errors shall be logged as provided by the quality assurance and monitoring plan developed pursuant to rule 9.10(147,155A) and shall be categorized as follows:

a. Computer order entry error;

b. Incorrect drug;

c. Incorrect dose;

d. Incorrect quantity — extra dose(s);

e. Incorrect quantity — short dose(s);

f. Incorrect dosage form;

g. Other errors. All errors categorized as "other errors" shall include additional notation identifying the error.

9.16(2) *Initial report to the board.* The first quarterly report to the board shall summarize identified errors by category and shall include the total number of errors identified, the reasons for the errors, the corrective actions taken to prevent the recurrence of those errors, and the average accuracy (correct doses over total doses) determined for all AMDS-dispensed drugs during the first quarter following implementation.

9.16(3) *Random verification.* If the average accuracy of the AMDS during the initial 60-day period is at least 99.7 percent for all drug doses dispensed, the quality assurance plan shall provide for random verification by a pharmacist. The plan shall provide that 5 percent of all drug doses dispensed daily utilizing the AMDS be verified by a pharmacist, or it shall provide that 100 percent of all drug doses dispensed on a specific day each month be verified by a pharmacist. A pharmacy may petition the board pursuant to 657—Chapter 34 for a variance for an alternate pharmacist verification process. Errors shall continue to be identified and logged as provided by the quality assurance and monitoring plan developed pursuant to rule 9.10(147,155A) and shall be categorized as provided in subrule 9.16(1).

If the average accuracy of the AMDS during the initial 60-day period is not at least 99.7 percent for all drug doses dispensed, the pharmacy shall continue pharmacist verification of all drug doses dispensed utilizing the AMDS until the average accuracy for 60 consecutive days is at least 99.7 percent.

9.16(4) *Reports during first year.* For a minimum of one year following implementation of the AMDS, written quarterly reports shall be submitted to the board. Reports shall summarize identified errors by category and shall include the total number of errors identified, the reasons for the errors, the corrective actions taken to prevent the recurrence of those errors, and the average accuracy (correct doses over total verified doses) for all drug doses verified during the preceding quarter.

9.16(5) *Accuracy.* Any random verification disclosing accuracy of less than 99.7 percent for all drug doses verified shall require that a pharmacist again verify all drug doses dispensed utilizing the AMDS until the average accuracy equals or exceeds 99.7 percent for all drug doses dispensed for three consecutive days.

9.16(6) *Continued verification.* The quality assurance plan shall provide for continuation, as long as the pharmacy utilizes the AMDS, of random verification by the pharmacist of AMDS-dispensed drug doses as provided in subrules 9.16(3) and 9.16(5).

9.16(7) *Reports after one year.* Following the one-year period and within 30 days of determining by random verification that the accuracy of AMDS drug fills is less than 99.7 percent for all drug doses verified, a written report shall be submitted to the board. The report shall summarize the identified errors by category and shall include the reasons for the errors, the corrective actions taken to prevent the recurrence of those errors, and the low accuracy rate prompting the report.

657—9.17(147,155A) Outpatient AMDS.

9.17(1) *Verification.* All outpatient prescriptions prepared for dispensing utilizing an AMDS shall be verified, prior to being dispensed, by a pharmacist in the pharmacist's physical presence unless a waiver is approved pursuant to subrule 9.17(2) or as provided in these rules for telepharmacy.

9.17(2) *Waiver.* A pharmacy may request waiver or variance from subrule 9.17(1) pursuant to the procedures and requirements of 657—Chapter 34. In addition to the requirements for the petition for waiver or variance identified in 657—Chapter 34, applications for waiver shall specify and include justification for the requested waiver, the methods to be used to ensure patient counseling is provided on new prescriptions pursuant to 657—8.20(155A), a quality assurance plan, and written policies and procedures for utilization of the AMDS.

a. Quarterly reports. The quality assurance plan shall provide for submission of written quarterly reports to the board. All reports shall summarize identified errors by category and shall include the reasons for the errors, the corrective actions taken to resolve and prevent recurrence of the errors, and the average accuracy for the specified period.

b. Verification. The quality assurance plan shall provide for verification processes for all AMDS-dispensed prescriptions.

c. Identification of errors. The quality assurance plan shall require that all identified errors be logged as provided by the quality assurance and monitoring plan developed pursuant to rule 9.10(147,155A) and shall be categorized as follows:

(1) Incorrect drug;
(2) Incorrect quantity;
(3) Incorrect dose;
(4) Incorrect dosage form;

(5) Incorrect directions for use;
(6) Incorrect patient name;
(7) Other incorrect label information;
(8) Computer order entry error;
(9) Other errors. All errors categorized as "other errors" shall include additional notation identifying each error.

d. Accuracy. The performance improvement plan shall identify actions to be taken in the event that any drug error is identified.

657—9.18(124,155A) Remote dispensing site operations.

9.18(1) *Automated pharmacy system.* On any day when the remote site is opened and prior to providing telepharmacy services, the managing pharmacy shall perform a test of the automated pharmacy system with the remote site to ensure proper operation. A log shall be created and maintained that includes the date and the test results and that identifies the individual performing the test.

9.18(2) *Remote site staffing.* A remote dispensing site shall be staffed by one or more qualified certified pharmacy technicians under the continuous supervision of a pharmacist at the managing pharmacy at all times that the remote site is open to provide telepharmacy services. Continuous supervision does not require the pharmacist to be physically present at the remote dispensing site, but the pharmacist shall supervise telepharmacy operations electronically through the automated pharmacy system.

9.18(3) *Supervising pharmacists.* The managing pharmacy shall have a sufficient number of pharmacists on duty to ensure that a pharmacist is able to provide all services offered by the managing pharmacy and to ensure appropriate supervision of all telepharmacy services. The board may limit the number of remote dispensing sites under the management of a single managing pharmacy.

9.18(4) *Prescription drug orders.* A remote dispensing site may receive written or electronic prescription drug orders or refill requests in accordance with the policies and procedures designated by the pharmacist in charge. As provided in policies and procedures, the qualified certified pharmacy technician at the remote site shall either transmit the prescription drug order or refill request to the managing pharmacy or input the prescription drug order or refill request so that the pharmacist at the managing pharmacy may perform a prospective drug use review and verify the prescription information prior to authorizing dispensing at the remote site. A pharmacy technician at a remote site shall not receive oral prescription drug orders from a prescriber or prescriber's agent. Oral prescription drug orders shall be communicated directly to a pharmacist.

9.18(5) *Drug use review.* A pharmacist at the managing pharmacy shall conduct a drug use review as specified in 657—8.21(155A) prior to authorizing delivery of the prescription to the patient or the patient's caregiver at the remote dispensing site.

9.18(6) *Prescription label.* A prescription dispensed at a remote site shall be labeled with the following information:

a. Serial number (a unique identification number of the prescription) which shall, in some manner, identify the remote site that dispensed the prescription.
b. The name and address of the remote dispensing site.
c. The name, address, and telephone number of the managing pharmacy.
d. The name of the patient or, if such drug is prescribed for an animal, the species of the animal and the name of the owner.
e. The name of the prescribing practitioner.
f. The date on which the prescription is dispensed.
g. The directions or instructions for use, including precautions to be observed.
h. The initials or other unique identification of the supervising pharmacist at the managing pharmacy and of the technician who dispenses the prescription at the remote dispensing site.
i. The name, strength, and quantity of the drug dispensed.

(1) If a pharmacist selects an equivalent drug product for a brand name drug product prescribed by a practitioner, the prescription container label shall identify the generic drug and may identify the brand name drug for which the selection is made, such as "(generic name) Generic for (brand name product)."

(2) If a pharmacist selects a brand name drug product for a generic drug product prescribed by a practitioner, the prescription container label shall identify the brand name drug product dispensed and may identify the generic drug product ordered by the prescriber, such as "(brand name product) for (generic name)."

9.18(7) *Verification prior to dispensing.* A pharmacist at the managing pharmacy shall approve each prescription before it leaves the remote site. If the qualified certified pharmacy technician at the remote site enters original or new prescription information into the automated pharmacy system, the pharmacist at the managing pharmacy shall, prior to approving dispensing of the drug via the AMDS, verify the information entered against an electronic or video image of the original prescription. The technician may transmit the prescription to the pharmacist by scanning the prescription into the automated pharmacy system provided that the means of scanning, transmitting, or storing the image shall not obscure the prescription information or render the prescription information illegible due to security features of the paper utilized by the prescriber to prepare the original prescription. Alternatively, the technician may make the original prescription available to the pharmacist by placing the prescription in an appropriate position to facilitate viewing of the original prescription with video communication between the remote site and the managing pharmacy. Using the video communication component of the automated pharmacy system, the pharmacist shall verify the accuracy of the drug dispensed and shall check the prescription label for accuracy. The dispensing record, the patient profile, and the prescription label shall identify both the pharmacist who approved dispensing the prescription and the certified pharmacy technician who completed the dispensing and delivery of the prescription to the patient.

9.18(8) *Patient counseling.* A remote dispensing site shall contain an appropriate area for patient counseling. The area shall be readily accessible to patients and be designed to maintain the confidentiality and privacy of a patient's conversation with the pharmacist. A pharmacist at the managing pharmacy shall utilize the video and audio components of the automated pharmacy system to counsel each patient or the patient's caregiver on all new prescriptions pursuant to 657—6.14(155A). As provided in subrule 9.5(4), a sign shall be posted at the remote site to ensure that all patients are informed that a pharmacist will provide counseling regarding any prescription dispensed from the remote site. A nonpharmacist may not extend an offer to counsel or ask questions of a patient or the patient's caregiver if such offer is intended to screen or limit the patient's interaction with a pharmacist.

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657—9.19 Reserved.

657—9.20(124,155A) Drugs at a remote dispensing site. Policies and procedures of the managing pharmacy shall establish criteria for the delivery and storage of drugs at the remote dispensing site including but not limited to the provisions of this rule. If controlled substances are maintained or dispensed from the remote dispensing site, the transfer of those controlled substances from the managing pharmacy to the remote site shall comply with federal and state requirements for the sale or transfer of controlled substances between registrants, including the use of DEA Form 222 for the transfer of Schedule II controlled substances.

9.20(1) *Drug delivery and verification.* Drugs shall only be delivered to the remote dispensing site in a sealed container with a list identifying the drugs, including drug strength and quantities, included in the container. Drugs shall not be delivered to the remote site unless a remote site staff member designated by the pharmacist in charge to receive and check the drugs is present at the remote site to accept delivery and verify that the drugs sent were actually received. The designated individual who receives and checks the order shall document the verification by signing and dating the list of drugs delivered.

9.20(2) *Limited drug inventory.* A remote dispensing site may maintain a limited drug inventory for the purpose of restocking the AMDS. The pharmacist at the managing pharmacy shall ensure, through

use of the electronic audio and video communications system or bar code technology, that the qualified certified pharmacy technician has accurately and correctly restocked drugs into AMDS components.

9.20(3) *Drug storage.* Drugs at a remote dispensing site shall be stored in a manner to protect their identity and integrity including the requirements of 657—Chapter 8 relating to environment, temperature, and handling of outdates. Drugs shall be stored in a secure area, and access to any drugs maintained at a remote site shall be limited to pharmacists from the managing pharmacy and qualified certified pharmacy technicians who have been so authorized, in writing, by the pharmacist in charge.

657—9.21(124,155A) Record keeping. In addition to records identified elsewhere in state and federal laws and regulations, the following records of a managing pharmacy and a remote dispensing site shall be maintained as provided herein.

9.21(1) *Electronic records.* All electronic records shall be available to, and accessible from, both the managing pharmacy and the remote dispensing site.

9.21(2) *Receipt, dispensing, and distribution records.* Except as provided in this subrule, a managing pharmacy shall maintain a record of all drugs received, dispensed, and distributed from the managing pharmacy and from each remote dispensing site.

a. Records of the receipt, dispensing, and distribution of controlled substances from a remote dispensing site, including controlled substances inventory records for the remote site, that are required by the DEA to be maintained at the registered location shall be maintained at the remote site.

b. Records of the managing pharmacy and of each remote dispensing site shall be maintained separately from each other.

These rules are intended to implement Iowa Code sections 147.107, 155A.13, and 155A.33.

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