

CHAPTER 21
ELECTRONIC DATA AND AUTOMATED SYSTEMS IN PHARMACY PRACTICE

657—21.1(124,155A) Purpose and scope. The purpose of this chapter is to provide the minimum standards for the utilization of electronic data and automated systems in the practice of pharmacy and shall apply to all pharmacies located in Iowa.

[ARC 3640C, IAB 2/14/18, effective 3/21/18]

657—21.2(124,155A) Definitions. For the purpose of this chapter, the following definitions shall apply:

“Automated data processing system” means an application that is used for prescription, patient, drug, and prescriber information; installed on a pharmacy’s computer or server; and controlled by the pharmacy.

“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. *“AMDS”* does not include electronic storage devices that do not have an electronic interface with one or more computers of the pharmacy.

“CSA” means the Iowa uniform controlled substances Act.

“CSA registration” means the registration issued by the board pursuant to the CSA that signifies the registrant’s authorization to engage in registered activities with controlled substances.

“DEA” means the U.S. Department of Justice, Drug Enforcement Administration.

“Electronically prepared prescription” means a prescription that is generated utilizing an electronic prescription application.

“Electronic device” means an electronic, mechanical, or other device which is used to intercept communications and includes but is not limited to network, file and print servers; desktop workstations; laptop computers; tablets; mini-computers; smart phones; and similar devices.

“Electronic prescription” means an electronically prepared prescription that is authorized and transmitted from the prescriber to the pharmacy by means of electronic transmission.

“Electronic prescription application” means software that is used to create electronic prescriptions and that is intended to be installed on a prescriber’s computers and servers where access and records are controlled by the prescriber.

“Electronic signature” means a confidential personalized digital key, code, number, or other method used for secure electronic data transmissions which identifies a particular person as the source of the message, authenticates the signatory of the message, and indicates the person’s approval of the information contained in the transmission.

“Electronic transmission” means the transmission of an electronic prescription, formatted as an electronic data file, from a prescriber’s electronic prescription application to a pharmacy’s computer, where the data file is imported into the pharmacy prescription application.

“Facsimile transmission” or *“fax transmission”* means the transmission of a digital image of a prescription from the prescriber or the prescriber’s agent to the pharmacy. *“Facsimile transmission”* includes but is not limited to transmission of a written prescription between the prescriber’s fax machine and the pharmacy’s fax machine; transmission of an electronically prepared prescription from the prescriber’s electronic prescription application to the pharmacy’s fax machine or printer; or transmission of an electronically prepared prescription from the prescriber’s fax machine to the pharmacy’s fax machine, computer, or printer.

“Intermediary” means any technology system that receives and transmits an electronic prescription between the prescriber and the pharmacy.

“Pharmacist verification” or *“verified by a pharmacist”* means the accuracy of a prescription drug is verified by a pharmacist, pharmacist-intern, or technician in an approved technician product verification program.

“*Prescription drug order*” or “*prescription*” means a lawful order of a practitioner for a drug or device for a specific patient that is communicated to a pharmacy, regardless of whether the communication is oral, electronic, via facsimile, or in printed form.

“*Readily retrievable*” means that hard-copy or electronic records can be separated out from all other records within 72 hours of a request from the board or other authorized agent.

“*Written prescription*” means a prescription that is created on paper, a prescription that is electronically prepared and printed, or a prescription that is electronically prepared and transmitted from the prescriber’s electronic device to a pharmacy via facsimile. A written prescription for a controlled substance shall be manually signed by the prescriber in compliance with federal and state laws, rules, and regulations.

[ARC 3640C, IAB 2/14/18, effective 3/21/18; ARC 4580C, IAB 7/31/19, effective 9/4/19; ARC 5007C, IAB 3/25/20, effective 4/29/20]

657—21.3(124,155A) System security and safeguards. To maintain the integrity and confidentiality of patient records and prescription drug orders, any system, computer, or electronic device utilized shall have adequate security including system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records and prescription drug orders. Authentication credentials shall be securely maintained by the individual to whom the credentials are issued and shall not be shared with or disclosed to any other individual. Once a drug or device has been dispensed, any alterations in either the prescription drug order data or the patient record shall be documented and shall include the identification of all pharmacy personnel who were involved in making the alteration as well as the responsible pharmacist. An automated data processing system used for the receipt and processing of electronic transmissions from a prescriber’s electronic prescription application shall comply with DEA requirements relating to electronic prescriptions and shall be certified compliant with DEA regulations.
[ARC 3640C, IAB 2/14/18, effective 3/21/18]

657—21.4 Reserved.

657—21.5(124,155A) Automated data processing systems. An automated data processing system may be used, subject to the requirements contained in this rule, for the storage and retrieval of prescription, patient, prescriber and drug data as well as data relating to the pharmacy staff utilization of the system.

21.5(1) *Electronic storage of hard-copy prescriptions.* A pharmacy that maintains an electronic copy of an original hard-copy prescription for a noncontrolled substance shall retain, in a readily retrievable format, the original hard-copy prescription as required in rule 657—6.8(155A) but shall be exempt from the requirement to record on the original hard-copy prescription the date and unique identification number of the prescription.

21.5(2) *Data retrievable and printable.* Any automated data processing system shall be capable of immediate retrieval (via computer monitor or hard-copy printout) of, at a minimum, any prescription, patient, prescriber, and drug data as well as data relating to pharmacy staff utilization of the system.

21.5(3) *Auxiliary procedure for system downtime.* A pharmacy utilizing an automated data processing system shall have a procedure that will maintain security and confidentiality of all data as well as ensure the legal dispensing of any prescription drug order in the event the system experiences downtime.

[ARC 3640C, IAB 2/14/18, effective 3/21/18]

657—21.6(124,155A) Electronic prescription applications. Beginning January 1, 2020, each prescription for a controlled substance shall be transmitted electronically to a pharmacy except as provided in rule 657—21.8(124,155A). Prior to January 1, 2020, a prescriber may, but shall not be required to, initiate and authorize a prescription drug order utilizing an electronic prescription application that has been determined to maintain security and confidentiality of patient information and records and, if prescribing controlled substances via an electronic prescribing system, certified compliant with DEA regulations for electronic prescribing of controlled substances. The prescription

drug order shall contain all information required by Iowa Code sections 155A.27 and 147.107(5). The receiving pharmacist shall be responsible for verifying the authenticity of an electronically prescribed prescription pursuant to rule 657—8.19(124,126,155A). A prescription that is electronically generated prior to January 1, 2020, or subject to exemption as provided in rule 657—21.8(124,155A), may be transmitted to a pharmacy via electronic or facsimile transmission or printed in hard-copy format for delivery to the pharmacy. A prescription that is transmitted by a prescriber's agent via electronic or facsimile transmission shall include the first and last names and title of the agent responsible for the transmission.

21.6(1) *Electronic transmission.* Beginning January 1, 2020, a prescription prepared pursuant to this rule shall be transmitted electronically to a pharmacy, unless exempt pursuant to rule 657—21.8(124,155A). A pharmacy shall be certified compliant with DEA regulations relating to electronic prescriptions prior to electronically receiving prescriptions for controlled substances. The electronic record shall serve as the original record and shall be maintained for two years from the date of last activity on the prescription. Any annotations shall be made and retained on the electronic record.

a. An electronically prepared and transmitted prescription that is printed following transmission shall be clearly labeled as a copy, not valid for dispensing.

b. The authenticity of a prescription transmitted via electronic transmission between a DEA-certified electronic prescription application and a DEA-certified electronic automated data processing system shall be deemed verified by virtue of the security processes included in those applications.

c. A pharmacy shall ensure that no intermediary has the ability to change the content of the prescription drug order or compromise its confidentiality during the transmission process. The electronic format of the prescription drug order may be changed by the intermediary to facilitate the transmission between electronic applications as long as the content of the prescription drug order remains unchanged.

d. In addition to the information requirements for a prescription, an electronically transmitted prescription shall identify the transmitter's telephone number for verbal confirmation, the telephone number where the prescriber can be contacted for timely consultation about patient care matters, the time and date of transmission, and the pharmacy intended to receive the transmission as well as any other information required by federal or state laws, rules, or regulations.

e. If the transmission of an electronic prescription fails, the prescriber may print the prescription, manually sign the printed prescription, and deliver the prescription to the pharmacy via facsimile transmission in accordance with subrule 21.6(2).

21.6(2) *Printed (hard-copy) prescriptions.* A prescription electronically generated prior to January 1, 2020, or a prescription that is exempt from the electronic prescription mandate as provided in rule 657—21.8(124,155A), may be printed in hard-copy format for facsimile transmission or delivery to the pharmacy.

a. A prescription for a controlled substance shall include the prescriber's manual signature. Printed or hard-copy prescriptions for Schedule II controlled substances shall not be transmitted to a pharmacy via facsimile transmission, except as authorized in rule 657—21.7(124,155A).

b. If the prescriber authenticates a prescription for a noncontrolled prescription drug utilizing an electronic signature, the printed prescription shall be printed on security paper. Security features of the paper shall ensure that prescription information is not obscured or rendered illegible when transmitted via facsimile or when scanned into an electronic record system.

c. If the facsimile transmission of a printed prescription is a result of a failed electronic transmission, the facsimile shall indicate that it was originally transmitted to the named pharmacy, the date and time of the original electronic transmission, and the fact that the original transmission failed.

[ARC 3640C, IAB 2/14/18, effective 3/21/18; ARC 4580C, IAB 7/31/19, effective 9/4/19; ARC 5350C, IAB 12/30/20, effective 2/3/21]

657—21.7(124,155A) *Facsimile transmission of a prescription.* A pharmacist may dispense noncontrolled and controlled drugs, including Schedule II controlled substances only as provided in this rule, pursuant to a prescription faxed to the pharmacy by the prescribing practitioner or the

practitioner's agent. The means of transmission via facsimile shall ensure that prescription information is not obscured or rendered illegible due to security features of the paper utilized by the prescriber to prepare a written prescription. The faxed prescription shall serve as the original record, except as provided in subrule 21.7(1), shall be maintained for a minimum of two years from the date of the last activity on the prescription, and shall contain all information required by Iowa Code sections 155A.27 and 147.107(5), including the prescriber's signature. If the prescription is transmitted by an agent of the prescriber, the facsimile transmission shall include the first and last names and title of the agent responsible for the transmission. The pharmacist shall be responsible for verifying the authenticity of the prescription as to the source of the facsimile transmission.

21.7(1) *Schedule II controlled substances—emergency situations.* A pharmacist may, in an emergency situation as defined in 657—subrule 10.26(1), dispense a Schedule II controlled substance pursuant to a facsimile transmission to the pharmacy of a written, signed prescription from the prescriber or the prescriber's agent pursuant to the requirements of rule 657—10.26(124). The facsimile shall serve as the temporary written record required by 657—subrule 10.26(2).

21.7(2) *Schedule II controlled substances—compounded injectable.* A prescription for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be transmitted by a prescriber or the prescriber's agent to a pharmacy via facsimile.

21.7(3) *Schedule II controlled substances—long-term care facility patients.* A prescription for any Schedule II controlled substance for a resident of a long-term care facility, as "long-term care facility" is defined in rule 657—23.2(155A), may be transmitted by the prescriber or the prescriber's agent to a pharmacy via facsimile. The prescription shall identify that the patient is a resident of a long-term care facility.

21.7(4) *Schedule II controlled substances—hospice patients.* A prescription for any Schedule II controlled substance for a patient in a hospice program licensed pursuant to Iowa Code chapter 135J or a program certified or paid for by Medicare under Title XVIII may be transmitted via facsimile by the prescriber or the prescriber's agent to the pharmacy. The prescription shall identify that the patient is a hospice patient.

[ARC 3640C, IAB 2/14/18, effective 3/21/18; ARC 5350C, IAB 12/30/20, effective 2/3/21]

657—21.8(124,155A) Electronic prescription mandate and exemptions. Beginning January 1, 2020, all prescriptions shall be transmitted electronically to a pharmacy except as provided in this rule.

21.8(1) *Prescriptions exempt.* Prescriptions which shall be exempt from electronic transmission include:

- a. A prescription for a patient residing in a nursing home, long-term care facility, correctional facility, or jail.
- b. A prescription authorized by a licensed veterinarian.
- c. A prescription for a device.
- d. A prescription dispensed by a department of veterans affairs pharmacy.
- e. A prescription requiring information that makes electronic transmission impractical, such as complicated or lengthy directions for use or attachments.
- f. A prescription for a compounded preparation containing two or more components.
- g. A prescription issued in response to a public health emergency in a situation where a non-patient-specific prescription would be permitted.
- h. A prescription issued for an opioid antagonist pursuant to Iowa Code section 135.190 or a prescription issued for epinephrine pursuant to Iowa Code section 135.185.
- i. A prescription issued during a temporary technical or electronic failure at the location of the prescriber or pharmacy, provided that a prescription issued pursuant to this paragraph shall indicate on the prescription that the prescriber or pharmacy is experiencing a temporary technical or electronic failure.
- j. A prescription issued pursuant to an established and valid collaborative practice agreement, standing order, or drug research protocol.

k. A prescription issued in an emergency situation pursuant to federal law and regulation and rules of the board. An emergency situation may include, but is not limited to, the issuance of a prescription to meet the immediate care need of a patient after hours when a prescriber is unable to access electronic prescribing capabilities. Such prescription shall be limited to a quantity sufficient to meet the acute need of the patient with no authorized refills.

21.8(2) *Prescriber, medical group, institution, or pharmacy exemption.* A prescriber, medical group, institution, or pharmacy which has been granted an exemption to the electronic prescription mandate pursuant to rule 657—21.9(124,155A) shall be exempt from the electronic prescription mandate only for the duration of the approved exemption. Upon expiration of an approved exemption, the prescriber, medical group, institution, or pharmacy shall either comply with the electronic prescription mandate or timely petition the board for renewal of the exemption pursuant to rule 657—21.9(124,155A).

[ARC 4580C, IAB 7/31/19, effective 9/4/19]

657—21.9(124,155A) Exemption from electronic prescription mandate—petition. A prescriber, medical group, institution, or pharmacy that is unable to comply with the electronic prescription mandate in rule 657—21.8(124,155A) prior to January 1, 2020, may petition the board, on forms provided by the board, for an exemption from the requirements based upon economic hardship; technical limitations that the prescriber, medical group, institution, or pharmacy cannot control; or other exceptional circumstances. A prescriber, medical group, institution, or pharmacy seeking an exemption beginning January 1, 2020, shall submit a completed petition no later than October 1, 2019. A timely petition for renewal of a previously approved exemption shall be submitted at least 60 days in advance of the expiration of the previously approved exemption.

21.9(1) *Petition information.* A petition for exemption from the electronic prescription mandate shall include, but not be limited to, all of the following:

a. The name and address of the prescriber, medical group, institution, or pharmacy seeking the exemption. For medical groups and institutions, a list of the names, professional license numbers, and CSA registration numbers of all prescribers who would be covered by the exemption.

b. Whether the petitioner is seeking an exemption for controlled substance prescriptions, non-controlled substance prescriptions, or both.

c. The petitioner's current electronic prescribing capabilities.

d. The reason, such as economic hardship, technological limitations, or other exceptional circumstances, the petitioner is seeking exemption.

e. Supporting documentation to justify the reason for the exemption, including the following mandatory documentation:

(1) For economic hardship petitions, a copy of the petitioner's most recent tax return showing annual income and at least two quotes documenting the cost of implementing electronic prescribing.

(2) For technological limitation petitions, documentation showing the available Internet service providers, the speed and bandwidth available from each provider, and any data caps imposed by the Internet service provider, and documentation showing the minimum technological requirements from at least two electronic prescribing platform vendors.

f. Anticipated date of compliance with the electronic prescription mandate.

g. If the petition seeks renewal of a previously approved exemption, information relating to the petitioner's actions during the previous exemption period to work toward compliance with the electronic prescription mandate or an explanation as to why no progress has been made.

21.9(2) *Criteria for board consideration of a petition.* The board shall consider all information provided in a petition seeking exemption to the electronic prescription mandate and shall approve or deny a petition for exemption based on the following criteria:

a. If the reason for exemption is economic hardship, whether the cost of compliance with the electronic prescription mandate would exceed 5 percent of the petitioner's annual income as reported on the petitioner's most recent tax return.

b. If the reason for exemption is technological limitations, whether the Internet service providers available have the technological capabilities required by the electronic prescribing platform.

c. If the reason for exemption is other exceptional circumstances, examples of exceptional circumstances include, but are not limited to, whether the petitioner is a free or low-income clinic, whether the petitioner had a bankruptcy in the previous year, whether the petitioner intends to discontinue practice in Iowa prior to December 31, 2020, and whether the petitioner has a disability that limits the ability to utilize an electronic prescribing platform. All other exceptional circumstances will be evaluated on a case-by-case basis.

d. If the petition seeks renewal of a previous exemption to the electronic prescription mandate, the number of exemptions previously granted and updated information as it relates to the petitioner working toward compliance with the electronic prescription mandate or the explanation as to why no progress has been made.

21.9(3) Duration of approved exemption. The board may approve an exemption, or the renewal of an exemption, to the electronic prescription mandate for a specified period of time not to exceed one year from the date of approval.

[ARC 4580C, IAB 7/31/19, effective 9/4/19]

657—21.10(124,155A) Automated medication distribution system (AMDS). Any pharmacy that utilizes an AMDS shall comply with these rules in addition to all applicable federal and state laws, rules, and regulations.

21.10(1) Policies and procedures. Pursuant to the requirements regarding policies and procedures in 657—subrule 8.3(5), each pharmacy utilizing an AMDS shall have policies and procedures that address all aspects of the operation of the AMDS to include, at a minimum:

- a. Access to drugs and patient information,
- b. Pharmacy personnel training in the proper operation of the AMDS,
- c. Methods to ensure accurate stocking of the AMDS pursuant to subrule 21.10(2),
- d. Confidentiality of patient information,
- e. Routine and preventative maintenance of the AMDS according to manufacturer recommendations,
- f. Packaging and labeling of prescription drugs loaded into or dispensed from the AMDS that is in compliance with federal and state laws, rules, and regulations, and
- g. Security and control of the prescription drugs maintained and utilized in the AMDS to include:
 - (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.

21.10(2) Stocking the AMDS. The pharmacy shall have adequate procedures in place to ensure the accurate stocking of drugs into an AMDS using barcode scanning technology. Only a pharmacy technician, pharmacist-intern, or pharmacist shall be allowed to participate in the stocking of the AMDS.

21.10(3) Pharmacist verification of drugs dispensed from AMDS.

a. When an AMDS only dispenses drugs that were prepackaged and verified by a pharmacist prior to being stocked in the AMDS and there was no further manipulation of the drug or package other than affixing a patient-specific label, such drugs shall not require additional pharmacist verification prior to administration or dispensing to the patient or authorized representative.

b. When a drug is stocked in an AMDS and undergoes further manipulation, such as counting and packaging, such drugs shall require pharmacist verification prior to dispensing to the patient. Such verification shall be documented.

21.10(4) Placement of AMDS.

a. An AMDS placed outside a pharmacist's direct supervision shall only dispense pharmacist-verified packages in compliance with paragraph 21.10(3) "a."

b. An AMDS that manipulates, including but not limited to counting, packaging, or labeling, prescription drugs for subsequent patient dispensing shall only be utilized in a pharmacy under the direct supervision of a pharmacist, except in an approved telepharmacy pursuant to 657—Chapter 13.
[ARC 3640C, IAB 2/14/18, effective 3/21/18]

657—21.11(124,155A) Pharmacist verification of controlled substance fills—daily printout or logbook. The individual pharmacist who makes use of the pharmacy prescription application shall provide documentation of the fact that the fill information entered into the pharmacy prescription application each time the pharmacist fills a prescription order for a controlled substance is correct. If the pharmacy prescription application provides a hard-copy printout of each day's controlled substance prescription order fill data, that printout shall be verified, dated, and signed by each individual pharmacist who filled a controlled substance prescription order. Each individual pharmacist must verify that the data indicated is correct and sign this document in the same manner as the pharmacist would sign a check or legal document (e.g., J. H. Smith or John H. Smith). This document shall be maintained in a separate file at that pharmacy for a period of two years from the dispensing date. This printout of the day's controlled substance prescription order fill data shall be generated by and available at each pharmacy using a computerized pharmacy prescription application within 48 hours of the date on which the prescription was dispensed. The printout shall be verified and signed by each pharmacist involved with such dispensing. In lieu of preparing and maintaining printouts as provided above, the pharmacy may maintain a bound logbook or separate file. The logbook or file shall include a statement signed each day by each individual pharmacist involved in each day's dispensing that attests to the fact that the prescription information entered into the pharmacy prescription application that day has been reviewed by the pharmacist and is correct as shown. Pharmacist statements shall be signed in the manner previously described. The logbook or file shall be maintained at the pharmacy for a period of two years after the date of dispensing.

[ARC 3640C, IAB 2/14/18, effective 3/21/18]

These rules are intended to implement Iowa Code sections 124.301, 124.306, 124.308, 147.107, 155A.27, 155A.33, and 155A.35.

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