CHAPTER 21
ELECTRONIC DATA IN PHARMACY PRACTICE

657—21.1(124,155A) Definitions. For the purpose of this chapter, the following definitions shall apply:

"Application service provider" means an entity that sells electronic prescription or pharmacy prescription applications as a hosted service where the entity controls access to the application and maintains the software and records on its servers.

"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 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, computer, 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.

"Pharmacy prescription application" means software that is used to process prescription information, is installed on a pharmacy's computers or servers, and is controlled by the pharmacy.

"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, facsimile, or in printed form.

"Readily retrievable" means that records kept by automatic data processing applications or other electronic or mechanized record-keeping systems can be separated out from all other records within a reasonable time not to exceed 48 hours of a request from the board or other authorized agent or that hard-copy records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

"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 9912B**, IAB 12/14/11, effective 1/18/12]

657—21.2(124,155A) System security and safeguards. To maintain the integrity and confidentiality of patient records and prescription drug orders, any system or computer 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. A pharmacy prescription application 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 9912B**, IAB 12/14/11, effective 1/18/12]

657—21.3(124,155A) Verifying authenticity of an electronically prepared or electronically or fax transmitted prescription. The pharmacist shall ensure the validity of the prescription as to its source of origin.

21.3(1) *Authentication measures.* Measures to be considered in authenticating prescription drug orders received via electronic transmission or fax transmission, or signed utilizing an electronic signature include but may not be limited to:

a. Maintenance of a practitioner number reference or electronic signature file.

b. Verification of the telephone number of the originating facsimile equipment or oral communication device.

c. Telephone verification with the practitioner's office that the prescription was both issued by the practitioner and transmitted by the practitioner or the practitioner's authorized agent.

d. Use of authentication processes approved by the DEA for controlled substances prescriptions.

e. Other efforts which, in the professional judgment of the pharmacist, may be necessary to ensure that the transmission was initiated by the prescriber.

21.3(2) *Prescription originally electronically transmitted.* When a pharmacist receives a written or oral prescription that indicates the prescription was originally electronically transmitted to a pharmacy, the pharmacist shall check with the pharmacy to which the prescription was originally electronically transmitted to determine whether the prescription was received and dispensed.

a. If the pharmacy that received the original electronic prescription dispensed the original prescription, the pharmacist receiving the written prescription shall mark the written prescription as void and shall not dispense the written prescription.

b. If the pharmacy that received the original electronic prescription has not dispensed the prescription, the pharmacy receiving the original electronic prescription shall mark the electronic prescription as void and shall not dispense the electronic prescription. The pharmacy that received the written or oral prescription shall dispense the prescription.
[**ARC 9912B**, IAB 12/14/11, effective 1/18/12]

657—21.4(124,155A) Automated data processing system. An automated data processing system may be used, subject to the requirements contained in this rule, for the storage and retrieval of original and refill information for prescription orders.

21.4(1) *On-line retrieval of prescription information.* Any computerized system shall provide on-line retrieval (via CRT display and hard-copy printout) of original prescription order information and refill history information. This shall include, but is not limited to, the following:

a. Original prescription number;

b. Date of issuance of the original prescription order by the practitioner;

c. Date and quantity of initial fill;

d. Date and quantity of each refill or partial fill, if applicable, and the total number of refills dispensed to date;

e. Full name and address of the patient;

f. Name, address, and, if a controlled substance, DEA registration number of the prescriber;

g. Name, strength, dosage form, quantity of the drug or device prescribed, and the total number of refills authorized by the prescribing practitioner; and

h. For each fill or refill, the identification code, name, or initials of the dispensing pharmacist.

21.4(2) *Printout of prescription fill data.* Any computerized system shall have the capability of producing a printout of any prescription fill data the user pharmacy is responsible for maintaining or producing under state and federal laws, rules and regulations. This would include a refill-by-refill audit trail for any specified strength and dosage form of any prescription drug by brand or generic name or both. Records maintained or provided in electronic format shall be sortable by prescriber name, patient name, drug dispensed, and date filled. Any computerized system employed by a user pharmacy shall be capable of providing at the pharmacy a printout or electronic file of the records in a format that is readily understandable to the board or other authorized agents. A pharmacy may contract with an application service provider, or the pharmacy may maintain computer servers at a remote location, but all required records shall be readily retrievable at the pharmacy if requested by the board or other authorized agent. The printout or electronic record shall include the following:

a. Name of the prescribing practitioner;
b. Name and address of the patient;
c. Quantity dispensed on each fill;
d. Date of dispensing for each fill;
e. Name or identification code of the dispensing pharmacist; and
f. The number of the original prescription order.

21.4(3) *Auxiliary procedure for system downtime.* In the event that a pharmacy utilizing a computerized system experiences system downtime, the pharmacy shall have an auxiliary procedure that will be used for documentation of fills and refills of prescription orders. This auxiliary procedure shall ensure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is retained for online data entry when the computer system is again available for use. As soon as reasonably possible upon resuming use of the computerized system, entry of all appropriate data accumulated during the system downtime shall be completed.

21.4(4) *Prescription notations.* When a pharmacist fills an electronic prescription that would require the pharmacist to make a notation on the prescription if the prescription were a written prescription, the pharmacist shall make the same notation electronically and shall retain the annotation electronically in the prescription record or in linked files.

21.4(5) *Records for electronic prescriptions for controlled substances.* A pharmacy that processes electronic prescriptions for controlled substances shall use a pharmacy prescription application that complies with DEA requirements relating to electronic prescriptions and that has been certified compliant with DEA regulations. When a prescription is received electronically from a prescriber's electronic prescription application into the pharmacy prescription application, the prescription and all required annotations shall be retained electronically.

[**ARC 9912B**, IAB 12/14/11, effective 1/18/12]

657—21.5(124,155A) Pharmacist verification of controlled substance refills—daily printout or logbook. The individual pharmacist who makes use of the pharmacy prescription application shall provide documentation of the fact that the refill information entered into the pharmacy prescription application each time the pharmacist refills an original written, fax, or oral 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 refill data, that printout shall be verified, dated, and signed by each individual pharmacist who refilled 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 refill 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 refill 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 refill 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 the appropriately authorized refill.
[**ARC 9912B**, IAB 12/14/11, effective 1/18/12]

657—21.6 Reserved.

657—21.7(124,155A) Electronically prepared prescriptions. A prescriber may initiate and authorize a prescription drug order utilizing a computer or other electronic communication or recording device. The prescription drug order shall contain all information required by Iowa Code section 155A.27. The receiving pharmacist shall be responsible for verifying the authenticity of an electronically transmitted prescription or of an electronic signature as provided by rule 657—8.19(124,126,155A) or 657—21.3(124,155A).

21.7(1) *Controlled substances.* A prescription for a controlled substance prepared pursuant to this rule may be transmitted to a pharmacy via facsimile transmission as provided by rule 657—21.9(124,155A) or rules 657—21.12(124,155A) through 657—21.16(124,155A). The transmitted prescription shall include the prescriber's original signature or electronic signature. A prescription for a controlled substance may be transmitted by a prescriber to a pharmacy via electronic transmission pursuant to DEA requirements for electronic prescribing of controlled substances. Both the prescriber's electronic prescription application and the pharmacy prescription application shall be certified compliant with DEA regulations for electronic prescriptions. An electronically prepared prescription shall not be electronically transmitted to the pharmacy if the prescription has been printed prior to the electronic transmission. An electronically prepared and electronically transmitted prescription that is printed following the electronic transmission shall be clearly labeled as a copy only, not valid for dispensing.

21.7(2) *Noncontrolled prescription drugs.* A prescription for a noncontrolled prescription drug prepared pursuant to this rule may be transmitted to a pharmacy via electronic transmission as provided in rule 657—21.8(124,155A) or via facsimile transmission as provided in rule 657—21.9(124,155A). The transmitted prescription shall include the prescriber's original signature or electronic signature.

21.7(3) *Printed (hard-copy) prescriptions.* A prescription prepared pursuant to this rule may be printed by the prescriber or prescriber's agent for delivery to a pharmacy. An electronically prepared and electronically transmitted prescription that is printed following the electronic transmission shall be clearly labeled as a copy, not valid for dispensing.

a. A prescription for a controlled substance shall include the prescriber's original signature.

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 that is designed to prevent photocopying or other duplication of the printed prescription by prominently disclosing the word "void" or "copy" on the duplication or by including a watermark or background that will not appear on duplication. If a watermark or background is used, the prescription shall include a statement that unless the watermark or background appears, the prescription is not valid. Security paper that complies with the security requirements of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, shall be deemed to comply with the security requirements of this paragraph.

c. When a prescription prepared pursuant to this subrule is transmitted to a pharmacy via facsimile, or when a prescription prepared pursuant to this subrule is scanned into an electronic record system, the watermark or background will not appear or the word "void" or "copy" will appear. The means of transmission via facsimile and the means of scanning into an electronic record system shall ensure that prescription information is not obscured or rendered illegible due to security features of the paper utilized by the prescriber to prepare the prescription. It is the responsibility of the pharmacist to verify the validity of the prescription as provided by rule 657—8.19(124,126,155A) or 657—21.3(124,155A).
[**ARC 7636B**, IAB 3/11/09, effective 4/15/09; **ARC 9912B**, IAB 12/14/11, effective 1/18/12]

657—21.8(124,155A) Electronic transmission of a prescription. Prescription drug orders may be communicated directly from a prescriber's computer or other electronic device utilizing an electronic prescription application to a pharmacy prescription application by electronic transmission. The receiving pharmacist shall be responsible for verifying the authenticity of an electronically transmitted prescription or of an electronic signature as provided by rule 657—8.19(124,126,155A) or 657—21.3(124,155A). The authenticity of a prescription transmitted via electronic transmission between a DEA-certified electronic prescription application and a DEA-certified electronic pharmacy prescription application shall be deemed verified by virtue of the security processes included in those applications.

21.8(1) *Secure transmission and patient's choice.* Orders shall be sent only to the pharmacy of the patient's choice, and no intermediary shall 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. This subrule does not prohibit the receiving pharmacist from amending or adding to the content of a prescription as necessary in compliance with federal and state laws, rules, or regulations.

21.8(2) *Information required.* In addition to the information requirements for a prescription, an electronically transmitted prescription drug order shall identify the transmitter's telephone number for verbal confirmation, 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.

21.8(3) *Who may transmit.* Orders shall be initiated and authorized only by a prescriber licensed and authorized under state law to prescribe the drug or device identified in the prescription and shall include the prescriber's electronic signature. An order for a controlled substance shall include the prescriber's DEA registration number. Orders may be transmitted by the prescriber or the prescriber's agent. An order transmitted by the prescriber's agent shall include the agent's first and last names and title.

21.8(4) *Original prescription.* The electronic transmission shall be deemed the original prescription drug order provided it meets the requirements of this rule. The electronic transmission of a prescription drug order for a controlled substance shall meet all requirements of the DEA for electronic prescribing. An electronically prepared and transmitted prescription shall be maintained electronically in the prescriber's electronic prescription application and the pharmacy prescription application for a minimum period of two years following the date of last activity on that prescription record. Once a prescription is created and transmitted electronically, the prescription record shall not be printed and retained as a hard-copy record.

21.8(5) *Failure of electronic transmission.* If the transmission of an electronic prescription fails, the intermediary shall notify the prescriber of that transmission failure and the prescriber may print the prescription, manually sign the printed prescription, and deliver the prescription to the pharmacy via facsimile transmission. The faxed prescription 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 9912B**, IAB 12/14/11, effective 1/18/12]

657—21.9(124,155A) Facsimile transmission (fax) of a prescription. A pharmacist may dispense noncontrolled and controlled drugs, excluding Schedule II controlled substances, pursuant to a prescription faxed to the pharmacy by the prescribing practitioner or the practitioner's agent. A pharmacist may dispense a Schedule II controlled substance to fill an emergency prescription authorization pursuant to the requirements of rule 657—10.22(124). 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 drug order shall serve as the original prescription, shall be maintained for a minimum of two years from the date of last fill or refill, and shall contain all information required by Iowa Code section 155A.27, including the prescriber's signature or electronic signature. The faxed prescription drug order, if transmitted by the practitioner's agent, shall identify the transmitting agent by first and last

names and title and shall include the prescriber's signature or electronic signature. A prescription for a controlled substance shall include the prescriber's manual signature. If the controlled substance prescription is not manually signed by the prescriber, the pharmacist shall orally verify the authenticity and the content of the prescription by contacting the prescriber or the prescriber's agent via telephone. The receiving pharmacist shall be responsible for verifying the authenticity of an electronically transmitted prescription or of an electronic signature as provided by rule 657—8.19(124,126,155A) or 657—21.3(124,155A). This rule shall not apply to a prescription drug order transmitted pursuant to 657—paragraph 8.15(1)*"d."*

[**ARC 7636B**, IAB 3/11/09, effective 4/15/09; **ARC 8171B**, IAB 9/23/09, effective 10/28/09; **ARC 9912B**, IAB 12/14/11, effective 1/18/12]

657—21.10 and **21.11** Reserved.

657—21.12(124,155A) Prescription drug orders for Schedule II controlled substances. A pharmacist may dispense Schedule II controlled substances pursuant to an electronic transmission to the pharmacy of an electronically prepared prescription if both the prescriber's electronic prescription application and the pharmacy prescription application have been certified to comply with DEA requirements for electronic prescribing of controlled substances. Records of electronically prepared and transmitted prescriptions shall be maintained electronically. A pharmacist may dispense Schedule II controlled substances pursuant to facsimile transmission to the pharmacy of a written, signed prescription from the prescribing practitioner or the practitioner's agent provided that the original written, signed prescription is received by the pharmacist prior to the actual dispensing of the controlled substance. An emergency authorization transmitted to the pharmacy by the practitioner's agent shall include the first and last names and title of the individual who transmitted the prescription. The means of transmission 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 original prescription shall be verified against the transmission at the time the substance is actually dispensed, shall be properly annotated, and shall be retained with the electronic transmission for filing.

[**ARC 7636B**, IAB 3/11/09, effective 4/15/09; **ARC 9912B**, IAB 12/14/11, effective 1/18/12]

657—21.13(124,155A) Facsimile transmission of a prescription for Schedule II controlled substances—emergency situations. A pharmacist may in an emergency situation as defined in 657—subrule 10.22(1) dispense Schedule II controlled substances pursuant to a facsimile transmission to the pharmacy of a written, signed prescription from the prescribing practitioner or the practitioner's agent pursuant to the requirements of 657—10.22(124). The facsimile or a print of the facsimile transmission shall serve as the temporary written record required by 657—subrule 10.22(2).

[**ARC 9912B**, IAB 12/14/11, effective 1/18/12]

657—21.14(124,155A) Facsimile transmission of a prescription for Schedule II narcotic substances—parenteral. A prescription for a nonoral dosage unit of 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 practitioner or the practitioner's agent to the pharmacy via facsimile. If the prescription is transmitted by the practitioner's agent, the transmission shall include the first and last names and title of the individual who transmitted the prescription. The means of transmission 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 facsimile serves as the original written prescription.

[**ARC 7636B**, IAB 3/11/09, effective 4/15/09; **ARC 9912B**, IAB 12/14/11, effective 1/18/12]

657—21.15(124,155A) Facsimile transmission of 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 may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy via facsimile. If the prescription is transmitted by the practitioner's agent, the transmission shall include the first and last names and title of the individual who transmitted the prescription. The

means of transmission 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.

21.15(1) *Original prescription.* The facsimile serves as the original written prescription.

21.15(2) *Information required.* The patient's address on the prescription shall indicate that the address location is a long-term care facility.

[**ARC 7636B**, IAB 3/11/09, effective 4/15/09; **ARC 9912B**, IAB 12/14/11, effective 1/18/12]

657—21.16(124,155A) Facsimile transmission of Schedule II controlled substances—hospice patients. A prescription for a Schedule II controlled substance for a patient enrolled in a hospice care 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 practitioner or the practitioner's agent to the dispensing pharmacy. If the prescription is transmitted by the practitioner's agent, the transmission shall include the first and last names and title of the individual who transmitted the prescription. The means of transmission 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.

21.16(1) *Original prescription.* The facsimile serves as the original written prescription.

21.16(2) *Information required.* The practitioner or the practitioner's agent shall note on the prescription that the patient is a hospice patient.

[**ARC 7636B**, IAB 3/11/09, effective 4/15/09; **ARC 9912B**, IAB 12/14/11, effective 1/18/12]

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

[Filed 9/16/97, Notice 7/16/97—published 10/8/97, effective 11/12/97]
[Filed 7/31/98, Notice 5/20/98—published 8/26/98, effective 9/30/98]
[Filed 8/14/02, Notice 6/12/02—published 9/4/02, effective 10/9/02]
[Filed 10/22/04, Notice 3/31/04—published 11/10/04, effective 12/15/04]
[Filed 6/2/05, Notice 1/19/05—published 6/22/05, effective 7/27/05]
[Filed 6/2/05, Notice 3/16/05—published 6/22/05, effective 7/27/05]
[Filed 2/7/07, Notice 10/25/06—published 2/28/07, effective 4/4/07]
[Filed 8/3/07, Notice 6/20/07—published 8/29/07, effective 10/3/07]
[Filed ARC 7636B (Notice ARC 7448B, IAB 12/31/08), IAB 3/11/09, effective 4/15/09]
[Filed ARC 8171B (Notice ARC 7910B, IAB 7/1/09), IAB 9/23/09, effective 10/28/09]
[Filed ARC 9912B (Notice ARC 9671B, IAB 8/10/11), IAB 12/14/11, effective 1/18/12]