CHAPTER 21
ELECTRONIC DATA IN PHARMACY PRACTICE

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

"Electronic signature" means a confidential personalized digital key, code, or number used for secure electronic data transmissions which identifies and authenticates the signatory.

"Electronic transmission" means the transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment. "Electronic transmission" includes, but is not limited to, transmission by facsimile machine, transmission to a printer as provided in subrule 21.7(3), and transmission by computer link, modem, or other communication device.

"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, or in printed form.

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. 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.

657—21.3(124,155A) Verifying authenticity of an electronically transmitted prescription. The pharmacist shall ensure the validity of the prescription as to its source of origin. Measures to be considered in authenticating prescription drug orders received via electronic transmission or signed utilizing an electronic signature include:

1. Maintenance of a practitioner number reference or electronic signature file.
2. Verification of the telephone number of the originating facsimile equipment or oral communication device.
3. 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.
4. Other efforts which, in the professional judgment of the pharmacist, may be necessary to ensure that the transmission was initiated by the prescriber.

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;
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 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. In any computerized system employed by a user pharmacy, the central record-keeping location must be capable of providing the printout to the pharmacy within 48 hours. The printout 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 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 on-line 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.

657—21.5(124,155A) Pharmacist verification of controlled substance refills—daily printout or logbook. The individual pharmacist who makes use of the system shall provide documentation of the fact that the refill information entered into a computer each time the pharmacist refills an original prescription order for a controlled substance is correct. If the system 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 system 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 computer that day has been reviewed by the pharmacist and is correct as shown. Pharmacist statements shall be signed in the manner previously described. The log book or file shall be maintained at the pharmacy for a period of two years after the date of dispensing the appropriately authorized refill.

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 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 21.9(124,155A) or rules 21.12(124,155A) through 21.16(124,155A). The transmitted prescription shall include the prescriber's original signature or electronic signature.

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 computer-to-computer transmission as provided in rule 21.8(124,155A) or via facsimile transmission as provided in rule 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.

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.

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]

657—21.8(124,155A) Computer-to-computer transmission of a prescription. Prescription drug orders, excluding orders for controlled substances, may be communicated directly from a prescriber's computer to a pharmacy's computer prescription processing system 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 21.3(124,155A).

21.8(1) *Secure transmission and patient's choice.* Orders shall be sent only to the pharmacy of the patient's choice, and no unauthorized intervening person or other entity shall change the content of the prescription drug order or compromise its confidentiality during the transmission process.

21.8(2) *Information required.* The electronically transmitted 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 only by an authorized prescriber and shall include the prescriber's electronic signature. Orders may be transmitted by the prescriber or the prescriber's agent.

21.8(4) *Original prescription.* The electronic transmission shall be deemed the original prescription drug order provided it meets the requirements of this rule.

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. 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 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 name and title and shall include the prescriber's signature or electronic signature. 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—subrule 8.15(1), paragraph *"d."*
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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 a written, signed prescription from the prescribing practitioner provided that the original written, signed prescription is received by the pharmacist prior to the actual dispensing of the controlled substance. If the emergency authorization is transmitted to the pharmacy by the practitioner's agent, the transmission shall include the name 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.
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657—21.13(124,155A) Prescription drug orders 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 an electronic transmission to the pharmacy of a written, signed prescription from the prescribing practitioner pursuant to the requirements of 657—10.22(124). The facsimile or a print of the electronic transmission shall serve as the temporary written record required by 657—subrule 10.22(2).

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 name 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.
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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 name 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.
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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 name 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.

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