

CHAPTER 21
CONFIDENTIAL AND ELECTRONIC DATA IN
PHARMACY PRACTICE

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

“*Confidential information*” means information accessed or maintained by the pharmacy in the patient’s records which contains personally identifiable information including but not limited to prescription and medication information, prescriber name and address, diagnosis, allergies, disease state, and drug interactions, regardless of whether such information is communicated to or from the patient, is in the form of paper, is preserved on microfilm, or is stored on electronic media.

“*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 and transmission by computer link, modem, or other computer communication device.

“*Personally identifiable information*” means any information contained in the patient record which could identify the patient including but not limited to name, address, telephone number, and social security number.

“*Prescription drug order*” means a lawful order of a practitioner for a drug or device for a specific patient that is communicated to a pharmacy.

657—21.2(124,155A) Confidentiality and security of patient records and prescription drug orders.

21.2(1) Confidential information. As provided in 657—subrule 8.5(5), confidential information in the patient record, including the contents of any prescription or the therapeutic effect thereof or the nature of professional pharmaceutical services rendered to a patient; the nature, extent, or degree of illness suffered by any patient; or any medical information furnished by the prescriber, may be released only as follows:

- a. Pursuant to the express written consent or release of the patient or the order or direction of a court.
- b. To the patient or the patient’s authorized representative.
- c. To the prescriber or other licensed practitioner then caring for the patient.
- d. To another licensed pharmacist where the best interests of the patient require such release.
- e. To the board or its representative or to such other persons or governmental agencies duly authorized by law to receive such information.

A pharmacist shall utilize the resources available to determine, in the professional judgment of the pharmacist, that any persons requesting confidential patient information pursuant to this rule are entitled to receive that information.

21.2(2) Exceptions. Nothing in this rule shall prohibit pharmacists from releasing confidential patient information as follows:

- a. Transferring a prescription to another pharmacy.
- b. Providing a copy of a nonrefillable prescription to the person for whom the prescription was issued which is marked “For Information Purposes Only.”

c. Providing drug therapy information to physicians or other authorized prescribers for their patients.

21.2(3) *Storage 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 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) Manner of issuance of a prescription drug order. A prescription drug order may be transmitted from a prescriber to a pharmacy in written form, orally including telephone voice communication, or by electronic transmission in accordance with applicable federal and state law and rules or guidelines of the board.

21.3(1) *Verification of prescription drug order.* The pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of any prescription drug order consistent with federal and state law and rules and guidelines of the board. In exercising professional judgment, the prescribing practitioner and the pharmacist shall take adequate measures to guard against the diversion of prescription drugs and controlled substances through prescription forgeries.

21.3(2) *Transmitting agent.* The prescribing practitioner may authorize an agent to transmit to the pharmacy a prescription drug order orally or by electronic transmission provided that the identity of the transmitting agent is included in the order.

657—21.4(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 by electronic transmission.

21.4(1) Orders shall be sent only to the pharmacy of the patient's choice with no unauthorized intervening person or other entity controlling, screening, or otherwise manipulating the prescription drug order or having access to it.

21.4(2) 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 law or rules or guidelines of the board.

21.4(3) Orders shall be transmitted only by an authorized prescriber or the prescriber's agent and shall include the prescriber's electronic signature.

21.4(4) The electronic transmission shall be deemed the original prescription drug order provided it meets the requirements of this rule.

657—21.5(124,155A) Facsimile transmission of a prescription. A pharmacist may dispense non-controlled and controlled drugs, excluding Schedule II controlled substances, pursuant to a prescription transmitted to the pharmacy by the prescribing practitioner or the practitioner's agent.

21.5(1) *Prescription requirements.* The transmitted prescription drug order:

- a. Shall serve as the original prescription.
- b. Shall be maintained for a minimum of two years from the date of last fill or refill.
- c. Shall contain all information required by Iowa Code section 155A.27.

21.5(2) *Legitimate purpose.* The pharmacist shall ensure that the prescription has been issued for a legitimate medical purpose by an authorized practitioner acting in the usual course of the practitioner's professional practice.

21.5(3) *Verifying authenticity of a 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 include:

- a. Maintenance of a practitioner's facsimile number reference or other electronic signature file.
- b. Verification of the telephone number of the originating facsimile equipment.
- c. Telephone verification with the practitioner's office that the prescription was both written by the practitioner and transmitted by the practitioner or the practitioner's authorized agent.
- d. Other efforts which, in the professional judgment of the pharmacist, may be necessary to ensure the transmission was initiated by the prescriber.

657—21.6(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 the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance. 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 for filing.

657—21.7(124,155A) Prescription drug orders for Schedule II controlled substances—emergency situations. A pharmacist may, in an emergency situation as defined in 657—subrule 10.13(5), 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—10.13(124). The facsimile or a print of the electronic transmission shall serve as the temporary written record required in 657—subrule 10.13(2).

657—21.8(124,155A) Facsimile transmission of a prescription for Schedule II narcotic substances—parenteral. 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 practitioner or the practitioner's agent to the pharmacy via facsimile.

21.8(1) The facsimile serves as the original written prescription.

21.8(2) The facsimile transmission of a prescription drug order for oral dosage units of Schedule II narcotic substances is not authorized by this rule.

657—21.9(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.

21.9(1) The facsimile serves as the original written prescription.

21.9(2) The patient's address on the prescription shall indicate that the addressed location is a long-term care facility.

657—21.10(124,155A) Facsimile transmission of Schedule II controlled substances—hospice patients. A prescription for any Schedule II controlled substance for a resident of a hospice certified by Medicare under Title XVIII or licensed pursuant to Iowa Code chapter 135J may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy via facsimile.

21.10(1) The facsimile serves as the original written prescription.

21.10(2) The practitioner or the practitioner's agent shall note on the prescription that the patient is a hospice patient.

657—21.11(124,155A) Automated data processing system—controlled substances refill information. An automated data processing system may be used for the storage and retrieval of refill information for prescription orders for controlled substances in Schedules III, IV, and V subject to the requirements contained in this rule.

21.11(1) *On-line retrieval of original prescription information.* Any such proposed computerized system must provide on-line retrieval (via CRT display and hard-copy printout) of original prescription order information for those prescription orders which are currently authorized for refilling. 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 of initial fill;
- d. Full name and address of the patient;
- e. Name, address, and DEA registration number of the practitioner; and
- f. Name, strength, dosage form, quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing practitioner.

21.11(2) *On-line retrieval of current refill history.* Any such proposed computerized system must also provide on-line retrieval (via CRT display and hard-copy printout) of the current refill history for Schedule III, IV, or V controlled substance prescription orders. This shall include any prescriptions authorized for refill during the past six months. The refill history for each prescription shall include, but is not limited to, the following:

- a. Name of the controlled substance;
- b. Each date of refill;
- c. The quantity dispensed at each refill;
- d. The identification code, name, or initials of the dispensing pharmacist for each refill; and
- e. The total number of refills dispensed to date for that prescription order.

21.11(3) *Pharmacist verification and documentation.* Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order for a Schedule III, IV, or V controlled substance is correct must be provided by the individual pharmacist who makes use of such a system. If such a 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 the individual pharmacist who refilled such a prescription order. The individual pharmacist must verify that the data indicated is correct and then 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 must be provided to each pharmacy using such a computerized system within 72 hours of the date on which the refill was dispensed. It must be verified and signed by each pharmacist who is involved with such dispensing. In lieu of such a printout, the pharmacy shall maintain a bound logbook, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by the pharmacist and is correct as shown. Such a book or file must be maintained at the pharmacy employing such a system for a period of two years after the date of dispensing the appropriately authorized refill.

21.11(4) *Printout of refill data.* Any such computerized system shall have the capability of producing a printout of any refill data which the user pharmacy is responsible for maintaining 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 controlled substance either 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 sending the printout to the pharmacy within 48 hours. Such a printout shall include the following:

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

21.11(5) *Auxiliary procedure for system downtime.* In the event that a pharmacy which employs such a computerized system experiences system downtime, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of Schedule III, IV, and V controlled substance prescription orders. This auxiliary procedure must 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 as soon as the computer system is again available for use.

21.11(6) *Partial fills of Schedule II controlled substance prescriptions.* Records of partially filled Schedule II prescriptions as authorized in rule 657—10.13(124), if an automated data processing system is used for the storage and retrieval of such information, shall comply with the requirements of this rule for Schedule III, IV, and V prescription refill information.

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

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